

**The New Brunswick Drug Plan  
Special Authorization Criteria**

**ABATACEPT (ORENCIA)  
250mg vial for intravenous injection**

**Juvenile Rheumatoid Arthritis**

- For the treatment of Juvenile Rheumatoid Arthritis:
  - In children (age 6-17) with moderate to severe active polyarticular juvenile idiopathic arthritis/juvenile rheumatoid arthritis who are intolerant to, or who have not had an adequate response from etanercept.
  - Initial treatment is limited to a maximum of 16 weeks. Retreatment is permitted for children who demonstrated an adequate initial treatment response and who are experiencing a disease flare.

Clinical Notes:

- Intravenous infusion: initial IV infusion dose is administered at 0, 2, and 4 weeks then every 4 weeks thereafter.
- Abatacept will not be reimbursed in combination with anti-TNF agents.

Claim Note:

- Must be prescribed by a rheumatologist.

**ABATACEPT (ORENCIA)  
250mg vial for intravenous injection, and 125mg subcutaneous injection**

**Rheumatoid Arthritis**

- For patients with moderate to severe active rheumatoid arthritis who:
  - Have not responded to, or have had intolerable side-effects with, an adequate trial of combination therapy of at least two traditional DMARDs (disease modifying antirheumatic drugs). Combination DMARD therapy must include methotrexate unless contraindicated or not tolerated,  
OR
  - Are not candidates for combination DMARD therapy must have had adequate trial of at least three traditional DMARDs in sequence, one of which must have been methotrexate unless contraindicated

Clinical Notes:

- Intravenous infusion: initial IV infusion dose is administered at 0, 2, and 4 weeks then every 4 weeks thereafter.
- Subcutaneous injection: a single IV loading dose of up to 1000 mg/dose followed by 125 mg subcutaneous injection within a day, then once-weekly subcutaneous injections.
- Abatacept will not be reimbursed in combination with anti-TNF agents.

Claim Note:

- Must be prescribed by a rheumatologist.

**ABIRATERONE (ZYTIGA)  
250mg tablet**

In combination with prednisone for the treatment of metastatic prostate cancer (castration-resistant prostate cancer) in patients who:

- are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy,  
OR
- have received prior chemotherapy containing docetaxel after failure of androgen deprivation therapy.

**ACAMPROSATE CALCIUM (CAMPRAL)  
333mg tablet**

For the maintenance of abstinence from alcohol in patients with alcohol dependence who have been abstinent for at least four days, and who have contraindications to naltrexone (e.g. currently receiving opioids, acute hepatitis or liver failure).

Clinical Note:

- Treatment with acamprosate should be part of a comprehensive management plan that includes counseling.

**ACLIDINUM BROMIDE (TUDORZA GENUAIR)  
400mcg/act inhalation powder**

**Chronic Obstructive Pulmonary Disease**

- For the treatment of chronic obstructive pulmonary disease (COPD) if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).

- Coverage can be provided without a trial of short-acting agent if there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1 /FVC ratio < 0.7) and significant symptoms (i.e. Medical Research Council (MRC) Dyspnea Scale score of 3-5).
- Combination therapy with aclidinium bromide AND a long-acting beta2-adrenergic agonist/inhaled corticosteroid (LABA/ICS) will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (i.e. MRC score of 3-5)
  - AND
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids.

Clinical Note:

- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale). Spirometry reports from any point in time will be accepted.

Medical Research Council (MRC) Dyspnea Scale	
COPD Stage	Symptoms
MODERATE – MRC 3 to 4	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
SEVERE – MRC 5	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

**ADALIMUMAB (HUMIRA)  
40mg/0.8mL (50mg/mL) injection**

**Ankylosing Spondylitis**

- For the treatment of patients with moderate to severe ankylosing spondylitis (e.g. Bath AS Disease Activity Index (BASDAI) score  $\geq 4$  on 10 point scale) who:
  - Have axial symptoms\* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation or in whom NSAIDs are contraindicated
  - OR
  - Have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.
- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
  - A decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score
  - OR
  - Patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or “ability to return to work”)

Clinical Notes:

1. \*Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.
2. Adalimumab will not be reimbursed in combination with other anti-TNF agents

Claim Notes:

- Must be prescribed by a rheumatologist or internist
- Approval will be for a maximum of 6 months
- Approvals will be for a maximum dose of 40mg every two weeks

**Crohn’s Disease**

- For moderately to severely active Crohn's disease in patients who are refractory or have contraindications to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy.

Clinical Notes:

1. Eligible patients should receive an induction dose of 160mg followed by 80mg two weeks later.
2. Clinical response should be assessed four weeks after the first induction dose.

Claim Notes:

- Initial requests will be approved for a maximum of 12 weeks.
- Ongoing coverage for maintenance therapy will only be reimbursed for responders and for a dose not exceeding 40mg every two weeks.

### **Polyarticular Juvenile Idiopathic Arthritis (pJIA)**

- For the treatment of children (age 4-17) with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) who have had inadequate response to one or more disease modifying antirheumatic drugs (DMARDs).

#### Claim Note:

- Must be prescribed by a rheumatologist.

### **Psoriatic Arthritis**

- For the treatment of active psoriatic arthritis in patients who:
  - Have at least three active and tender joints, and
  - Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

#### Clinical Note:

- Should not be used in combination with other tumor necrosis factor (TNF) antagonists.

#### Claim Notes:

- Must be prescribed by a rheumatologist.
- The number of doses is limited to twenty-six 40 mg doses per year with no dose escalation permitted.

### **Rheumatoid Arthritis**

- For patients with moderate to severe active rheumatoid arthritis who:
  - Have not responded to, or have had intolerable side-effects with, an adequate trial of combination therapy of at least two traditional DMARDs (disease modifying antirheumatic drugs). Combination DMARD therapy must include methotrexate unless contraindicated or not tolerated,  
OR
  - Are not candidates for combination DMARD therapy must have had adequate trial of at least three traditional DMARDs in sequence, one of which must have been methotrexate unless contraindicated

#### Clinical Note:

- Should not be used in combination with other tumor necrosis factor (TNF) antagonists.

#### Claim Notes:

- Must be prescribed by a rheumatologist.
- The number of doses is limited to twenty-six 40 mg doses per year with no dose escalation permitted.

### **Plaque Psoriasis**

- Requests will be considered for treatment of patients with severe, debilitating chronic plaque psoriasis who meet all of the following criteria:
  - Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genital region;
  - Failure to respond to, contraindications to or intolerance to methotrexate and cyclosporine;
  - Failure to respond to, intolerance to or unable to access phototherapy

#### Clinical Notes:

1. Continuation of therapy beyond 16 weeks will be based on response. Patients not responding adequately at these time points should have treatment discontinued with no further treatment with the same agent recommended.
2. An adequate response is defined as either:
  - $\geq 75\%$  reduction in the Psoriasis Area and Severity Index (PASI) score from when treatment started (PASI 75),  
OR
  - $\geq 50\%$  reduction in the PASI score (PASI 50) with a  $\geq 5$  point improvement in the Dermatology Life Quality Index (DLQI) from when treatment started,  
OR
  - A quantitative reduction in BSA affected with qualitative consideration of specific regions such as face, hands, feet, or genital region.
3. Concurrent use of >1 biologic will not be approved

#### Claim Notes:

- Initial approval limited to 16 weeks.
- Must be prescribed by a dermatologist
- Approval limited to a dose of 80 mg administered once followed by 40 mg after 1 week of initial dose, then 40 mg every other week thereafter, up to a year (if response criteria met at 16 weeks).

### **ADEFOVIR DIPIVOXIL (HEPSERA and generic brand) 10mg tablet**

For the treatment of Hepatitis B when used in combination with lamivudine, in patients who have failed lamivudine, as defined by an increase in HBV DNA of  $\geq 1 \log_{10}$  IU/mL above the nadir, measured on two separate occasions within an interval of at least one month, after the first three months of lamivudine therapy, and when lamivudine failure is not due to poor adherence to therapy.

**AFATINIB DIMALEATE (GIOTRIF)  
20mg, 30mg and 40mg tablets**

For the first-line treatment of patients with EGFR mutation positive advanced or metastatic adenocarcinoma of the lung who have an ECOG performance status 0 or 1.

**Renewal Criteria:**

Written confirmation that the patient has responded to treatment and in whom there is no evidence of disease progression.

Clinical Note:

- Patients who receive afatinib 1st line are not eligible for erlotinib for 2nd line, 3rd line, or maintenance therapy).

Claim Notes:

- Approval duration: 6 months
- Doses of more than 40 mg once daily will not be approved.

**AFILBERCEPT (EYLEA)  
40mg/mL solution for intravitreal injection**

**1. Neovascular (wet) age-related macular degeneration (AMD)**

**Initial Coverage:**

For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) where all of the following apply to the eye to be treated:

- Best Corrected Visual Acuity (BCVA) is between 6/12 and 6/96
- The lesion size is less than or equal to 12 disc areas in greatest linear dimension
- There is evidence of recent (< 3 months) presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, or optical coherence tomography (OCT)
- Administration is to be done by a qualified ophthalmologist experienced in intravitreal injections.
- The interval between doses should not be shorter than 1 month.

**Continued Coverage:**

Treatment should be continued only in people who maintain adequate response to therapy.

Clinical Notes:

- Coverage will not be approved for patients:
  - With permanent retinal damage as defined by the Royal College of Ophthalmology guidelines
  - Receiving concurrent treatment with verteporfin.
- Aflibercept should be permanently discontinued if any one of the following occurs:
  - Reduction in BCVA in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology
  - Reductions in BCVA of 30 letters or more compared to either baseline and/or best recorded level since baseline as this may indicate either poor treatment effect, adverse events or both.
  - There is evidence of deterioration of the lesion morphology despite optimum treatment over 3 consecutive visits.

Claim Notes:

- An initial claim of up to two vials of aflibercept (1 vial per eye treated) will be automatically reimbursed when prescribed by an ophthalmologist. If additional medication is required, a request should be made through special authorization.
- Reimbursement will be limited to a maximum of 1 vial of aflibercept per eye treated every 30 days. Claims submitted for greater than 1 vial, or submitted within 30 days of a previous claim, will not be reimbursed.
- Please refer to [Quantities for Claims Submissions](#) for the correct unit of measure.

**2. Diabetic macular edema (DME)**

**Initial coverage:**

For the treatment of visual impairment due to diabetic macular edema (DME) in patients who meet all of the following criteria:

- clinically significant centre-involving macular edema for whom laser photocoagulation is also indicated
- hemoglobin A1c test in the past 6 months with a value of less than or equal to 11%
- best corrected visual acuity of 20/32 to 20/400
- central retinal thickness greater than or equal to 250 micrometers

**Renewal Criteria:**

- confirm that a hemoglobin A1c test in the past 6 months had a value of less than or equal to 11%
- date of last visit and results of best corrected visual acuity at that visit
- date of last OCT and central retinal thickness on that examination
- if aflibercept is being administered monthly, please provide details on the rationale

Clinical Notes:

- Treatment should be given monthly until maximum visual acuity is achieved (i.e. stable visual acuity for three consecutive months while on aflibercept). Thereafter, visual acuity should be monitored monthly.
- Treatment should be resumed when monitoring indicates a loss of visual acuity due to DME and continued until stable visual acuity is reached again for three consecutive months.

Claim Notes:

- Approval Period: 1 year
- Please refer to [Quantities for Claims Submissions](#) for the correct unit of measure.

**3. Central retinal vein occlusion (CRVO)**

For the treatment of visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO).

Clinical Notes:

- Treatment should be given monthly until maximum visual acuity is achieved (i.e. stable visual acuity for three consecutive months while on aflibercept). Thereafter, visual acuity should be monitored monthly.
- Treatment should be resumed when monitoring indicates a loss of visual acuity due to macular edema secondary to central retinal vein occlusion and continued until stable visual acuity is reached again for three consecutive months.

Claim Notes:

- Approval Period: 1 year
- Please refer to [Quantities for Claims Submissions](#) for the correct unit of measure.

**ALENDRONATE (generic brand)  
40mg tablet**

For the treatment of Paget's disease.

**ALGLUCOSIDASE ALFA (MYOZYME)  
50mg vial injection**

For the treatment of infantile-onset Pompe disease, as demonstrated by onset of symptoms and confirmed cardiomyopathy within the first 12 months of life.

Monitoring of therapy

The monitoring of markers of disease severity and response to treatment must include at least:

1. Weight, length and head circumference.
2. Need for ventilatory assistance, including supplementary oxygen, CPAP, BiPAP, or endotracheal intubation and ventilation.
3. Left ventricular mass index (LVMI) as determined by echocardiography (not ECG alone).
4. Periodic consultation with cardiology.
5. Periodic consultation with respiratory.

Withdrawal of therapy

1. Patients to be considered for reimbursement of drug costs for alglucosidase alfa treatment must be willing to participate in the long-term evaluation of the efficacy of treatment by periodic medical assessment. Failure to comply with recommended medical assessment and investigations may result in withdrawal of financial support of drug therapy.
2. The development of the need for continuing invasive ventilatory support after the initiation of ERT should be considered a treatment failure. Funding for ERT should not be continued for infants who fail to achieve ventilator-free status, or who deteriorate further, within 6 months after the initiation of ventilatory support.
3. Deterioration of cardiac function, as shown by failure of LV hypertrophy (as indicated by LV mass index) to regress by more than Z=1 unit, or persistent clinical or echocardiographic findings of cardiac systolic or diastolic failure without evidence of improvement, in spite of 24 weeks of ERT, should be considered a treatment failure and funding for ERT should be discontinued.

**ALMOTRIPTAN (AXERT and generic brands)  
6.25mg and 12.5mg tablets**

- For the treatment of migraine<sup>1</sup> headache of moderate<sup>2</sup> intensity when other therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective AND patients have not responded to oral sumatriptan, zolmitriptan, rizatriptan and naratriptan.
- For the treatment of migraine<sup>1</sup> headache of severe<sup>2</sup> or ultra severe<sup>2</sup> intensity when patients have not responded to oral sumatriptan, zolmitriptan, rizatriptan and/or naratriptan.

#### Clinical Notes:

1. <sup>1</sup> As diagnosed based on current Canadian guidelines.
2. <sup>2</sup> Definitions:
  - Moderate - pain is distracting causing need to slow down and limit activities;
  - Severe - pain affects ability to concentrate and very difficult to continue with daily activities;
  - Ultra severe - unable to speak or think clearly; not able to function; likely lying down or sleeping

#### Claim Notes:

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - patients with >3 migraines/month on average despite prophylactic therapy may be considered for up to a maximum of 12 doses / 30 days
- <sup>3</sup> Reimbursement will be available for a maximum quantity of triptan doses as outlined in criteria per 30 days regardless of the agent(s) used within the 30 day period.
- Special authorization for the products almotriptan 6.25mg and 12.5mg tablets, naratriptan 1mg and 2.5mg tablets, rizatriptan 5mg and 10mg tablets and wafers, sumatriptan 5mg and 20mg nasal spray and zolmitriptan 2.5mg tablets and orally dispersible tablets, 2.5mg and 5mg nasal spray will be considered as a set. Approvals will include all products in this list, however reimbursement will be available for a maximum quantity of one agent per month.

### **AMBRISENTAN (VOLIBRIS) 5mg and 10mg tablets**

For treatment of patients with pulmonary arterial hypertension (PAH), of at least World Health Organization (WHO) functional class III, which is associated with either idiopathic or connective tissue disease and who have failed to respond to or who have contraindications to, or who are not a candidate for sildenafil.

#### Clinical Notes:

1. Diagnosis of PAH should be confirmed by cardiac catheterization
2. Ambrisentan will not be approved when used concurrently with other endothelin receptor antagonists, epoprostenol, treprostinil or sildenafil.

#### Claim Note:

- The maximum dose of ambrisentan that will be reimbursed is 10mg daily

### **APIXABAN (ELIQUIS) 2.5mg and 5mg tablets**

#### **Atrial fibrillation**

For the prevention of stroke and systemic embolism in at-risk patients with non-valvular atrial fibrillation for whom:

- Anticoagulation is inadequate following at least a two month trial on warfarin;  
**OR**
- Warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

#### Clinical Notes:

- The following patient groups are excluded from coverage for apixaban for atrial fibrillation:
  - Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <25 mL/min)
  - Patients 75 years of age or older without documented stable renal function
  - Patients with hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis
  - Patients with prosthetic heart valves.
- At-risk patients with atrial fibrillation are defined as those with a CHADS<sub>2</sub> score of ≥ 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a CHADS<sub>2</sub> score of 1.
- Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
- Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months.
- The usual recommended dose is 5mg twice daily; a reduced dose of apixaban 2.5mg twice daily is recommended for patients with at least two of the following: age > 80 years, body weight < 60kg, or serum creatinine > 133 micromole/litre.
- Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see apixaban product monograph).
- Patients starting apixaban should have ready access to appropriate medical services to manage a major bleeding event.
- There is currently no data to support that apixaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves. As a result, apixaban is not recommended in these populations.

### **Venous thromboembolic events (VTE) treatment**

For the treatment of VTE (deep vein thrombosis (DVT) or pulmonary embolism (PE)).

#### Clinical Notes:

1. The recommended dose of apixaban for patients initiating DVT or PE treatment is 10mg twice daily for 7 days, followed by 5 mg twice daily.
2. Drug plan coverage for apixaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, apixaban 2.5mg twice daily is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.
3. Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

#### Claim Note:

- Approval Period: Up to 6 months

### **APIXABAN (ELIQUIS) 2.5mg tablet**

#### **VTE prophylaxis**

- For the prevention of venous thromboembolic events (VTE) in patients who have undergone elective total knee replacement (TKR) surgery.
- For the prevention of VTE in patients who have undergone elective total hip replacement (THR) surgery.

#### Clinical Notes:

1. The total duration of therapy includes the period during which doses are administered post-operatively in an acute care (hospital) setting, and the approval period is for the balance of the total duration after discharge.
2. The first dose is typically administered 12 to 24 hours after surgery, assuming adequate hemostasis has been achieved.
3. The ADVANCE clinical trial program did not evaluate the efficacy or safety of sequential use of molecular weight heparin followed by apixaban for the prophylaxis of VTE. Due to the current lack of evidence for sequential use, coverage is not intended for this practice.
4. Clinical judgment is warranted to assess the increased risk for VTE and/or adverse effects in patients with a history of previous VTE, myocardial infarction, transient ischemic attack or ischemic stroke; a history of intraocular or intracerebral bleeding; a history of gastrointestinal disease with gastrointestinal bleeding; moderate or severe renal insufficiency (estimated creatinine clearance <30 mL/min); severe liver disease; concurrent use of other anticoagulants; or age greater than 75 years.
5. Apixaban has not been studied in clinical trials in patients undergoing hip fracture surgery, and is not recommended in these patients.

#### Claim Notes:

- Maximum reimbursement without Special Authorization will be limited to 14 days of therapy (28 tablets) for TKR or 30 days of therapy (60 tablets) for THR, within a 6 month period.
- Subsequent reimbursement for prophylaxis within a 6 month period (i.e. second joint replacement procedure within the 6 month period) will require Special Authorization.

### **APREPITANT (EMEND)**

#### **80 mg and 125 mg capsules; Tri-Pack**

For the prevention of acute and delayed nausea and vomiting due to highly emetogenic cancer chemotherapy (e.g. cisplatin >70 mg/m<sup>2</sup>) in patients who have experienced emesis despite treatment with a combination of a 5-HT<sub>3</sub> antagonist and dexamethasone in a previous cycle of highly emetogenic chemotherapy.

#### Claim Note:

- Prescription claims for up to a maximum of 2 Tri-packs, or 6 capsules will be automatically reimbursed every 28 days when the prescription is written by an oncologist or an oncology clinical associate/general practitioners-oncology. If additional medication is required within a 28 day period subsequent to the initial prescription, a request should be made through special authorization.

### **ARIPIRAZOLE (ABILIFY)**

#### **2mg, 5mg, 10mg, 15mg, 20mg, 30mg tablets**

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients with a history of failure, intolerance, or contraindication to at least one less expensive antipsychotic agent.

**ARIPIRAZOLE (ABILIFY MAINTENA)  
300mg and 400mg vial**

For the treatment of schizophrenia in patients

- for whom compliance with oral antipsychotics presents problems
- OR
- who are currently receiving a typical depot antipsychotic and experiencing significant side effects (e.g. extrapyramidal symptoms or tardive dyskinesia) or lack of efficacy

**ASENAPINE (SAPHRIS)  
5mg, 10mg sublingual tablets**

For the acute treatment of manic or mixed episodes associated with bipolar I disorder as either:

- Monotherapy, after a trial of lithium or divalproex sodium has failed, and trials of less expensive atypical antipsychotic agents have failed due to intolerance or lack of response
- Co-therapy with lithium or divalproex sodium, after trials of less expensive atypical antipsychotic agents have failed due to intolerance or lack of response.

**ATOVAQUONE (MEPRON)  
750mg/5mL suspension**

For the treatment of mild to moderate *Pneumocystis Carinii* pneumonia in patients who are intolerant to trimethoprim-sulfamethoxazole.

**AXITINIB (INLYTA)  
1mg, 5mg tablets**

As a second-line treatment for patients with metastatic clear cell renal carcinoma, who, based on the mutual assessment of the treating physician and patient, are unable to tolerate ongoing use of an effective dose of everolimus or who have a contraindication to everolimus.

**AZITHROMYCIN (ZITHROMAX and generic brands)  
600mg tablet**

For the prevention of disseminated *Mycobacterium Avium Complex* (MAC) in HIV positive patients who are severely immunocompromised with CD4 levels  $<0.1 \times 10^9/L$ .

**BETAHISTINE (SERC and generic brands)  
8mg, 16mg and 24mg tablets**

For the symptomatic treatment of the recurrent episodes of vertigo associated with Ménière's disease.

**BOCEPREVIR (VICTRELIS)  
200mg capsule  
BOCEPREVIR/RIBAVIRIN PLUS PEGINTERFERON ALFA-2B (VICTRELIS TRIPLE)  
200mg / 200mg capsules plus 80mcg injection  
200mg / 200mg capsules plus 100mcg injection  
200mg / 200mg capsules plus 120mcg injection  
200mg / 200mg capsules plus 150mcg injection**

For the treatment of chronic hepatitis C genotype 1 infection in patients with compensated liver disease, in combination with peginterferon alpha and ribavirin, if the following criteria are met:

- Detectable levels of hepatitis C virus (HCV) RNA in the last six months
- Fibrosis stage of F2, F3 or F4 or on the recommendation of an Internal Medicine Specialist

Claim Note:

- One course of treatment only (for up to 44 weeks duration) will be approved.

**BOSENTAN (TRACLEER and generic brands)  
62.5mg and 125mg tablets**

For treatment of pulmonary arterial hypertension (PAH) in patients with World Health Organization (WHO) functional class III or IV

Clinical Notes:

1. Idiopathic pulmonary arterial hypertension (IPAH) in patients who do not demonstrate vasoreactivity on testing or who demonstrate vasoreactivity on testing but fail a trial of, or are intolerant to, calcium channel blockers.
2. Pulmonary arterial hypertension associated with connective tissue disease or congenital heart disease or human immunodeficiency virus (HIV) who do not respond adequately to conventional therapy.



**BUDESONIDE/FORMOTEROL (SYMBICORT)  
100mcg/6mcg and 200mcg/6mcg metered dose inhalers**

**Reversible Obstructive Airway Disease**

- For patients with reversible obstructive airways disease who are:
  - Stabilized on an inhaled corticosteroid and a long-acting beta2-adrenergic agonist,  
OR
  - Using optimal doses of inhaled corticosteroids but are still poorly controlled.

**Chronic Obstructive Pulmonary Disease**

- For the treatment of chronic obstructive pulmonary disease (COPD) if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).
- Coverage can be provided without a trial of short-acting agent if there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1 /FVC ratio < 0.7) and significant symptoms (i.e. Medical Research Council (MRC) Dyspnea Scale score of 3-5).
- Combination therapy with a long-acting muscarinic antagonist (LAMA) AND a long-acting beta2-adrenergic agonist/inhaled corticosteroid (LABA/ICS) will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms i.e. MRC score of 3-5)  
AND
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids.

Clinical Note:

- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale). Spirometry reports from any point in time will be accepted.

Medical Research Council (MRC) Dyspnea Scale

COPD Stage	Symptoms
MODERATE – MRC 3 to 4	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
SEVERE – MRC 5	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

**BUPRENORPHINE / NALOXONE (SUBOXONE and generic brands)  
2 mg/0.5 mg and 8 mg/2 mg sublingual tablets**

For the treatment of opioid dependence for patients in whom methadone is contraindicated (e.g. patients at high risk of, or with QT prolongation, or hypersensitivity to methadone).

Clinical Note:

- Commonly reported adverse effects associated with methadone therapy (e.g. sweating, constipation, insomnia, etc.) will not be considered to be hypersensitivity.

Claim Note:

- Requests from New Brunswick physicians authorized to prescribe methadone or physicians with experience in the treatment of opioid dependence will be considered.

**BUPROPION (ZYBAN)  
150mg tablet**

For smoking cessation treatment in adults 18 years of age and older.

A maximum of 12 weeks of standard therapy will be reimbursed annually without special authorization for either nicotine replacement therapy (patches/gum) or a non-nicotine, prescription smoking cessation drug (Champix or Zyban).

Claim Notes:

- A maximum of 168 tablets will be reimbursed annually without special authorization.
- Individuals who have a high probability of quitting with prolonged therapy may be approved under special authorization for 56 additional tablets. A maximum of three additional requests will be permitted annually (maximum of 168 additional tablets).

- All special authorization requests for additional tablets will require confirmation the individual has agreed, or is already registered with, the Smokers Helpline (1-877-513-5333) or is participating in another form of smoking cessation counselling to be specified.
- Requests for special authorization should be submitted on the [Request for Additional Smoking Cessation Therapy Form](#).

**Important Links:**

- [Smokers Helpline Referral Form](#)
- [Smokers Helpline Online](#)
- [On the road to quitting](#)
- [Quit4life](#)

**BUSERELIN ACETATE (SUPREFACT)  
1mg/mL nasal solution**

1. For the palliative treatment of stage D<sub>2</sub> carcinoma of the prostate.
2. For the hormonal management of endometriosis

Claim Notes:

- Approval period is limited to a maximum of 6 months.

**CABERGOLINE (DOSTINEX and generic brand)  
0.5mg tablets**

For the treatment of patients with hyperprolactinemia who have failed or are intolerant to bromocriptine

**CANAGLIFLOZIN (INVOKANA)  
100mg and 300mg tablets**

For the treatment of type 2 diabetes mellitus, in addition to metformin and a sulfonylurea, in patients with inadequate glycemic control on metformin and a sulfonylurea and for whom insulin is not an option.

**CAPECITABINE (XELODA and generic brand)  
150mg and 500mg tablets**

**Colorectal Cancer**

- For single agent therapy of colorectal cancer in patients who are chemotherapy naive or patients who have progressed 6 months after completion of adjuvant 5-FU/ leucovorin therapy. Coverage will be limited to:
  - a) Metastatic colorectal cancer, with an ECOG performance status of 0-2\*, when first line combination chemotherapy (5-FU/ leucovorin/irinotecan) is declined or not tolerated.
  - b) Stage III (Dukes' C) colon cancer and ECOG status 0-1<sup>†</sup> as adjuvant therapy.
- As part of the CAPOX (capecitabine-oxaliplatin) regimen for the first-line and second-line treatment of Metastatic Colorectal Cancer (mCRC) for patients with an ECOG performance status of 0-2\*.

**Metastatic Breast Cancer**

- For treatment of metastatic breast cancer where patients have progressed after prior chemotherapy and who have an ECOG performance status of 0-2\*.

Clinical Note:

- \*Patients who are asymptomatic and those who are symptomatic and in bed less than 50% of the time.

Claim Note:

- Prescriptions written by New Brunswick hematologists, oncologists or an oncology clinical associate/general practitioners-oncology do not require special authorization.

**CARVEDILOL (generic brands)  
3.125mg, 6.25mg, 12.5mg and 25mg tablets**

For the treatment of stable symptomatic heart failure in patients with a left ventricular ejection fraction (LVEF) less than or equal to 40%.

Claim Note:

- Prescriptions written by cardiologists or internists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

**CELECOXIB (CELEBEX and generic brands)  
100mg and 200mg capsules**

1. For the treatment of osteoarthritis and rheumatoid arthritis in patients who have at least one of the following risk factors:
  - Past history of ulcers
  - Concurrent warfarin therapy
  - Concurrent prednisone therapy
  - Failure or intolerance to at least two other NSAIDs (e.g. ibuprofen, diclofenac, naproxen)

Clinical Note:

- Recommended maximum daily doses:
    - 200mg for osteoarthritis
    - 400mg for rheumatoid arthritis
2. For patients who are at high risk of upper gastrointestinal (GI) complications and have had failure or intolerance to at least two other NSAIDs.
  3. For patients who have a documented history of ulcers proven radiographically and/or endoscopically.

Claim Note:

- Celecoxib is a regular benefit for patients age 65 and over.

**CHOLINESTERASE INHIBITORS (Donepezil, Galantamine, Rivastigmine)  
- For the treatment of mild to moderate Alzheimer's disease**

<p><b>To initiate therapy:</b> Requests must be submitted on the appropriate NB Drug Plans special authorization form. <a href="http://www.gnb.ca/0212/alzheimers-e.asp">http://www.gnb.ca/0212/alzheimers-e.asp</a></p>	
<p><b>For a patient being started on a first cholinesterase inhibitor (ChEI):</b></p>	<p>Patients who meet all of the following reimbursement criteria will be approved for <u>an initial 6 months</u> of therapy:</p> <ul style="list-style-type: none"> <li>• a diagnosis of probable Alzheimer's disease or possible Alzheimer's disease with vascular component or Lewy bodies;</li> <li>• a Mini Mental Score Exam (MMSE) score of 10 to 30; and</li> <li>• a Functional Assessment &amp; Staging Test (FAST) score of 4 to 5</li> </ul>
<p><b>For a patient who has previously taken no more than one other ChEI and is switching:</b></p>	<p>Patients will be approved for <u>an initial 6 months</u> of therapy with a <u>second</u> ChEI when the following information is provided:</p> <ul style="list-style-type: none"> <li>• the reason for discontinuing the first ChEI</li> </ul> <p>Requests to switch from one agent in the class to another will not be considered beyond the initial 6 month approval.</p>
<p><b>To continue therapy for 1 year period (once initial 6 month approval has been completed):</b></p> <p>Patients who meet the following monitoring criteria will be approved for <u>1 year periods</u> of therapy:</p> <ul style="list-style-type: none"> <li>• MMSE score of 10 to 30 (Note: MMSE score must be provided 6 months after starting a ChEI and then only annually thereafter.);</li> <li>• FAST score of 4 to 5 <u>AND</u> (Note: FAST score must be provided 6 months after starting a ChEI and then only annually thereafter.)</li> </ul> <p>Note: Monitoring of target symptoms will no longer be required; however, physicians will be asked at the initial and subsequent reassessments if, in their opinion, the patient is benefiting from the drug.</p>	

**CIPROFLOXACIN (CILOXAN and generic brand)  
0.3% ophthalmic solution and 0.3% ophthalmic ointment**

For the treatment of corneal ulcers and bacterial conjunctivitis.

Claim Note:

- Prescriptions written by New Brunswick ophthalmologists and optometrists do not require special authorization.

**CIPROFLOXACIN (CIPRO and generic brands)  
250mg, 500mg and 750mg tablets  
500mg/5mL Oral Suspension**

For the treatment of:

- Complicated urinary tract infections caused by resistant bacteria.
- Skin, soft tissue, bone and joint infections caused by Gram negative bacteria.
- Severe (“malignant”) otitis externa.
- Infections with *Pseudomonas aeruginosa* (susceptible strains – resistance is now common).

Claim Note:

- Prescriptions written by New Brunswick urologists, infectious disease specialists, medical oncologists, hematologists, respiratory medicine specialists or medical microbiologists do not require special authorization.

**CIPROFLOXACIN (CIPRO XL)  
1000mg tablets**

For the treatment of complicated urinary tract infection and acute uncomplicated pyelonephritis when alternative agents are ineffective, not tolerated or contraindicated.

Claim Note:

- Prescriptions written by New Brunswick urologists, infectious disease specialists and medical microbiologists do not require special authorization.

**CIPROFLOXACIN HCL / DEXAMETHASONE (CIPRODEX)  
0.3% / 0.1% otic suspension**

- For the treatment of acute otitis media with otorrhea through tympanostomy tubes who require treatment.
- For the treatment of acute otitis externa in the presence of a tympanostomy tube or known perforation of the tympanic membrane.

Claim Note:

- Prescriptions written by certified New Brunswick otolaryngologists do not require special authorization.

**CLOPIDOGREL (PLAVIX and generic brands)  
75mg tablet**

1. Secondary prevention of vascular ischemic events (myocardial infarction, stroke) in patients with a history of symptomatic atherosclerotic disease (including symptomatic peripheral artery disease) who have had treatment failure or are intolerant or allergic to ASA.
2. For the prevention of thrombosis post stent implantation for a period of up to 6 months for bare-metal stents (BMS) and 12 months for drug-eluting stents (DES).
3. For the prevention of vascular ischemic events in patients who have been hospitalized with acute coronary syndrome (i.e. unstable angina or non-ST segment elevation myocardial infarction) in combination with ASA for a period of three months. Longer term combination therapy may be considered for a period of 12 months post NSTEMI-ACS for patients:
  - with a second acute coronary syndrome within 12 months, or
  - with complex or extensive CAD (i.e. diffuse 3 vessel CAD not amenable to revascularization), or
  - who have had a previous stroke, transient ischemic attack or symptomatic PAD

Claim Note:

- Prescriptions written by cardiologists or vascular surgeons do not require special authorization.

**CODEINE (CODEINE CONTIN)  
50mg, 100mg, 150mg, and 200mg tablets (controlled release)**

For the treatment of mild to moderate cancer-related or chronic non-cancer pain.

**CRIZOTINIB (XALKORI)  
200mg and 250mg capsules**

Second-line therapy for patients with anaplastic lymphoma kinase (ALK) -positive advanced non-small cell lung cancer (NSCLC) with an ECOG performance status of 0-2.

**DABRAFENIB (TAFINLAR)  
50mg and 75mg capsules**

- As monotherapy for the first line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma with ECOG performance status of 0 or 1. If brain metastases are present, patients should be asymptomatic or stable.
- As monotherapy for the second line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma for patients who have progressed after receiving chemotherapy treatment in the first line setting with ECOG performance status of 0 or 1. If brain metastases are present, patients should be asymptomatic or stable.

Clinical Notes:

- Recommended Dose: 150 mg twice daily until disease progression or development of unacceptable toxicity requiring discontinuation of dabrafenib.
- Dabrafenib will not be reimbursed in patients who have progressed on a prior BRAF therapy.

Claim Notes:

- Initial approval duration: 6 months
- Renewal approval duration: 6 months

**DABIGATRAN (PRADAXA)  
110mg and 150mg capsules**

For the prevention of stroke and systemic embolism in at-risk patients with non-valvular atrial fibrillation for whom:

- Anticoagulation is inadequate following at least a two month trial of warfarin; or
- Warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy and at home).

Clinical Notes:

1. The following patient groups are excluded from coverage for dabigatran for atrial fibrillation:
  - Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate < 30 mL/min)
  - Patients 75 years of age or older without documented stable renal function
  - Patients with hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis
  - Patients with prosthetic heart valves
2. At-risk patients with atrial fibrillation are defined as those with a CHADS<sub>2</sub> score of ≥ 1
3. Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
4. Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see dabigatran Product Monograph).
5. Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate that maintained for at least three months (i.e. 30-49 mL/min for 110 mg twice daily dosing or ≥ 50 mL/min for 150 mg twice daily dosing).
6. There is currently no data to support that dabigatran provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so dabigatran is not recommended in these populations.
7. Patients starting dabigatran should have ready access to appropriate medical services to manage a major bleeding event.

**DALTEPARIN SODIUM (FRAGMIN)  
Pre-filled syringes, ampoule, single dose vial, and multidose vial**

See criteria under [Low Molecular Weight Heparins](#).

**DARBEPOETIN (ARANESP)  
10, 20, 30, 40, 50, 60, 80, 100, 130, 150, 200, 300 and 500mcg SingleJect® pre-filled Syringes**

- For the treatment of anemia associated with chronic renal failure.

Claim Note:

- Patients on dialysis (end-stage renal disease) receive darbepoetin through the dialysis units.
- For the treatment of transfusion dependent patients with hematologic malignancies whose transfusion requirements are ≥ 2 units of packed red blood cells per month over 3 months.

Clinical Note:

- Approval of further 12 week cycles is dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly.

Claim Note:

- Initial approval for 12 weeks.

**DARIFENACIN HYDROBROMIDE (ENABLEX)  
7.5mg and 15mg extended release tablets**

For the treatment of overactive bladder with symptoms of urgency, urgency incontinence, and urinary frequency in patients who have not tolerated a reasonable trial of immediate-release oxybutynin.

Clinical Note:

- Requests for the treatment of stress incontinence will not be considered.

Claim Note:

- If the patient has had a claim for oxybutynin in the previous 24 months, the adjudication system will recognize this information and the claim for darifenacin will be automatically reimbursed without the need for a written special authorization request.

**DASABUVIR PLUS OMBITASVIR, PARITAPREVR AND RITONAVIR (HOLKIRA PAK)  
250mg film-coated tablet + 12.5mg/75mg/50mg film-coated tablet**

For the treatment of chronic hepatitis C genotype 1 infection in adult patients.

<b>Genotype 1 Patient Population</b>	<b>Approval period</b>
Treatment naïve and experienced genotype 1b, non-cirrhotic*	12 weeks
Treatment naïve and experienced genotype 1a, non-cirrhotic	12 weeks in combination with RBV
Treatment naïve and experienced genotype 1b, cirrhotic	12 weeks in combination with RBV
Treatment naïve and experienced (prior relapsers and prior partial responders) genotype 1a, cirrhotic	12 weeks in combination with RBV
Treatment experienced genotype 1a, with cirrhosis AND who have had a previous null response to PegIFN and RBV	24 weeks in combination with RBV

\*Holkira Pak with ribavirin (RBV) is recommended in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.

Patients must also meet all of the following criteria:

1. Prescribed by a hepatologist, gastroenterologist or an infectious disease specialist (or other physician experienced in treating hepatitis C).
2. Lab-confirmed hepatitis C genotype 1, subtype 1a or 1b required.
3. Patient has a quantitative HCV RNA value within the last 6 months.
4. Fibrosis stage F2 or greater (Metavir scale or equivalent).

Exclusion Criteria:

- Patients currently being treated with another HCV antiviral agent.
- Patients who have received a previous treatment course of Holkira Pak (re-treatment requests will not be considered).
- Decompensated patients.
- Patients with a hepatitis C infection with a genotype other than 1a or 1b.
- Patients who have received previous NS3/4A protease inhibitor-based regimens (i.e. boceprevir, telaprevir and simeprevir based regimens).
- Patients who have received previous sofosbuvir-based regimens (including ledispavir/sofosbuvir).

Clinical notes:

1. Treatment-experienced patients are patients who have previously been treated with peginterferon / ribavirin (PegIFN/RBV) regimen, including regimens containing HCV protease inhibitors and did not receive adequate response.
2. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (5-6).
3. HIV-HCV co-infected patients may be considered as per criteria listed above.
4. For patients who require RBV (Moderiba™) as outlined above, it will be provided at no cost through AbbVie Care when prescribed in combination with Holkira Pak. RBV will not be covered by New Brunswick Drug Plans. Please contact AbbVie Care for more information at 1-844-471-CARE (2273).

Claim notes:

- Requests will be considered for individuals enrolled in Plans ADEFGV.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**DASATINIB (SPRYCEL)**  
**20mg, 50mg, 70mg, 80mg, 100mg, 140mg tablets**

**Chronic Myeloid Leukemia (CML)**

For adult patients with chronic phase CML

- with primary or acquired resistance to imatinib 600mg per day. Dosing recommendation: 100mg per day or 70mg two times daily
- who progress to accelerated phase on imatinib 600mg per day. Dosing recommendation: 140mg per day
- who have blast crisis while on imatinib 600mg per day. Dosing recommendation: 140mg per day
- who have intolerance to imatinib or have experienced grade 3 or higher toxicities to imatinib

Renewal Criteria:

- Request for renewal must specify how the patient has benefited from therapy and is expected to continue to do so.

Claim Notes:

- Initial approval period: 1 year
- Renewal period: 1 year

**Acute Lymphoblastic Leukemia (ALL)**

For adult patients with Philadelphia chromosome positive acute lymphoblastic leukemia (ALL) whose disease is resistant to imatinib-containing chemotherapy (patient must have tried 600mg/day) or have experienced grade 3 non-hematologic toxicity, or grade 4 hematologic toxicity persisting for more than 7 days as a result of therapy with imatinib.

Renewal Criteria:

- Written confirmation that the patient has benefited from therapy and is expected to continue to do so.

Claim Notes:

- Initial approval period: 1 year
- Renewal period: 1 year

**DEFERASIROX (EXJADE)**  
**125mg, 250mg and 500mg dispersible tablets for suspension**

For patients who require iron chelation but in whom deferoxamine is contraindicated.

**DENOSUMAB (PROLIA)**  
**60mg/mL pre-filled syringe**

- For the treatment of osteoporosis in postmenopausal women who would otherwise be eligible for coverage of oral bisphosphonate therapy and who have clinically or radiographically-documented fracture due to osteoporosis  
AND
- Contraindication to oral bisphosphonates for one of the following reasons:
  - immune-mediated hypersensitivity reaction to oral bisphosphonates;
  - OR
  - abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia.

Clinical Note:

- Please note that commonly reported adverse effects or intolerance to bisphosphonates will not be considered to be hypersensitivity.

**DENOSUMAB (XGEVA)**  
**120mg/1.7mL single use vial**

For the prevention of skeletal-related events (SREs) in patients with castrate-resistant prostate cancer (CRPC) with one or more documented bone metastases and an ECOG performance status of 0-2\*.

Clinical Note:

- \*Patients who are asymptomatic and those who are symptomatic and in bed less than 50% of the time.

**DESMOPRESSIN (DDAVP and generic brands)**  
**0.1mg and 0.2mg tablets**  
**DESMOPRESSIN (DDAVP MELT)**  
**60mcg, 120mcg and 240mcg tablets**

- For the management of diabetes insipidus.
- For the treatment of patients 18 years and older with nocturnal enuresis.

Claim Note:

- Desmopressin oral formulations are regular benefits for Plan D≤18.

**DESMOPRESSIN (DDAVP and generic brand)  
10µg/metered dose nasal spray and 0.1mg/mL intranasal solution**

- For the treatment of patients with diabetes insipidus.

Clinical Note:

- The nasal formulations are no longer indicated for nocturnal enuresis due to the risk of hyponatremia.

**DIENOGEST (VISANNE)  
2mg tablet**

For the management of pelvic pain associated with endometriosis in patients for whom one or more less costly hormonal options are either ineffective or cannot be used.

Clinical Note:

- Continuous combined oral contraceptives and medroxyprogesterone are examples of less costly hormonal options.

**DIMETHYL FUMARATE (TECFIDERA)  
120mg and 240mg delayed-release capsules**

For the treatment of relapsing-remitting multiple sclerosis (RRMS) in patients who meet the following criteria:

- Two disabling attacks of MS in the previous two years, and
- Ambulatory with or without aid (EDSS of less than or equal to 6.5)

Clinical Note:

- An attack is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 24 hours in the absence of fever, and preceded by stability for at least one month.

Claim Note:

- Prescriptions written by New Brunswick neurologists do not require special authorization.

**DIPYRIDAMOLE EXTENDED RELEASE/ASA IMMEDIATE RELEASE (AGGRENOX)  
200mg/25mg capsules**

For the secondary prevention of ischemic stroke/TIA in patients who have experienced a recurrent thrombotic event (stroke, symptoms of TIA) while taking ASA.

**DONEPEZIL (ARICEPT and generic brands)  
5mg and 10mg tablets**

See criteria under [Cholinesterase Inhibitors](#).

**DORNASE ALPHA RECOMBINANT (PULMOZYME)  
1 mg/mL solution**

For cystic fibrosis patients with a FEV<sub>1</sub><70% predicted with clinically significant decline in FEV<sub>1</sub> not responsive to usual treatment.

Claim Note:

- Requests will be considered for individuals enrolled in Plans ABDEFGV

**DULOXETINE (CYMBALTA)  
30 mg and 60 mg capsules**

**Diabetic Peripheral Neuropathic Pain**

For the treatment of peripheral neuropathic pain in diabetic patients who have failed treatment with at least 2 other less costly agents used for the treatment of neuropathic pain. (i.e. tricyclic antidepressants and/or an anticonvulsants).

**Major Depressive Disorder**

For the treatment of major depressive disorder in patients 18 years and older, who have failed treatment with at least one less costly antidepressant.

Claim Note:

- The maximum dose reimbursed is 60 mg daily.



**ECULIZUMAB (SOLIRIS)  
10mg/mL vial**

For the treatment of paroxysmal nocturnal hemoglobinuria (PNH).

Clinical Notes:

1. A Request for Coverage including the completed consent and specific special authorization forms must be submitted and the patient must:
  - a. Satisfy the Clinical Criteria for eculizumab (initial or continued coverage, as appropriate);
  - b. Not meet any of the criteria specified in Contraindications to Coverage or Discontinuance of Coverage.
2. Please contact the NB Drug Plans at 1-800-332-3691 for a packet containing the Clinical Criteria and required forms.

Claim Note:

- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**ELVITEGRAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE (STRIBILD)  
150mg/150mg/200mg/300mg tablet**

As a complete regimen for antiretroviral treatment naïve HIV-1 infected patients in whom efavirenz is not indicated.

Claim Note:

- Prescriptions written by NB Infectious Disease Specialists and Medical Microbiologists experienced in treating patients with HIV/AIDS, do not require special authorization.

**ENOXAPARIN SODIUM (LOVENOX)  
Pre-filled syringes and multi-dose vials  
ENOXAPARIN SODIUM (LOVENOX HP)  
Pre-filled syringes**

See criteria under [Low Molecular Weight Heparins](#).

**ENTECAVIR (BARACLUDE and generic brands)  
0.5mg tablets**

For the treatment of chronic hepatitis B infection in patients with cirrhosis documented on radiologic or histologic grounds and a HBV DNA concentration above 2,000 IU/mL.

**ENZALUTAMIDE (XTANDI)  
40mg capsules**

For treatment of patients with metastatic castration-resistant prostate cancer who:

- are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy and have not received prior chemotherapy,
- OR
- have progressed on docetaxel-based chemotherapy and would be an alternative to abiraterone for patients in the post-docetaxel setting

Clinical Notes:

- Patient must have no risk factors for seizures
- When used as first line treatment, patient must have an ECOG performance status  $\leq 1$
- When used as second line treatment, patient must have an ECOG performance status  $\leq 2$
- Will not be reimbursed in combination with abiraterone

**EPLERENONE (INSPIRA)  
25mg and 50mg tablets**

For the treatment of patients with New York Heart Association (NYHA) class II chronic heart failure with left ventricular systolic dysfunction (with ejection fraction  $\leq 35\%$ ), as a complement to standard therapy.

Clinical Note:

- Patients must be on optimal therapy with an angiotensin-converting-enzyme (ACE) inhibitor, an angiotensin-receptor blocker (ARB), or both and a beta-blocker (unless contraindicated) at the recommended dose or maximal tolerated dose.

**EPOETIN ALFA (EPREX)**

1000IU/0.5mL, 2000IU/0.5mL, 3000IU/0.3mL, 4000IU/0.4mL, 5000IU/.5mL, 6000IU/.6mL, 8000IU/.8mL, 10000IU/mL, 20000IU/mL, 30,000IU/0.75mL and 40000IU/mL vials and pre-filled syringes

1. Treatment of anemia associated with chronic renal failure.

Claim Note:

- Patients on dialysis (end-stage renal disease) receive epoetin through the dialysis units.
2. Treatment of transfusion dependent anemia related to therapy with zidovudine in HIV-infected patients.
  3. Treatment of transfusion dependent patients with hematologic malignancies whose transfusion requirements are  $\geq 2$  units of packed red blood cells per month over 3 months.

Clinical Note:

- Approval of further 12 week cycles is dependent on evidence of satisfactory clinical response or reduced treatment requirement to less than 2 units of PRBC monthly.

Claim Note:

- Initial approval for 12 weeks.

**EPOPROSTENOL SODIUM (CARIPUL and FLOLAN)**

0.5mg and 1.5mg vials for injection

1. For the treatment of World Health Organization (WHO) class III or IV idiopathic pulmonary arterial hypertension in patients who do not demonstrate vasoreactivity on testing or who demonstrate vasoreactivity on testing but fail a trial of, or are intolerant to, calcium channel blockers.
2. For the treatment of WHO class III or IV pulmonary arterial hypertension associated with scleroderma in patients who do not respond adequately to conventional therapy.

**ERLOTINIB (TARCEVA)**

25mg, 100mg and 150mg tablets

**Non-small Cell Lung Cancer (NSCLC)**

For the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen and whose EGFR mutation status is positive or unknown.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and in whom there is no evidence of disease progression.

Claim Notes:

- Initial approval period: 6 month trial
- Renewal period: 6 months

**ESTRADIOL-17 $\beta$  (ESTRADOT and generic brand)**

25 mcg, 37.5mcg, 50mcg, 75mcg and 100mcg transdermal patch

For the treatment of menopausal symptoms in women for whom oral forms of HRT are not tolerated or indicated.

**ETANERCEPT (ENBREL)**

25mg liquid injection

50mg/mL pre-filled syringe

**Ankylosing Spondylitis**

- For the treatment of patients with moderate to severe ankylosing spondylitis (e.g. Bath AS Disease Activity Index (BASDAI) score  $\geq 4$  on 10 point scale) who:
  - have axial symptoms\* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation or in whom NSAIDs are contraindicated
  - OR
  - have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.
- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
  - a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score;
  - OR

- patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work")

Clinical Notes:

1. \* Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial, disease do not require a trial of NSAIDs alone.
2. Etanercept will not be reimbursed in combination with other anti-TNF agents.

Claim Notes:

- Must be prescribed by a rheumatologist or internist
- Approval will be for a maximum of 6 months
- Approvals will be for a maximum dose of 50mg per week.

**Juvenile Rheumatoid Arthritis**

- For the treatment of children (age 4-17) with moderately to severely active polyarticular juvenile rheumatoid arthritis who have:
  - not responded to adequate treatment with one or more disease modifying antirheumatic drug (DMARD) for at least 3 months,
  - OR
  - intolerance to DMARDs

Claim Note:

- Must be prescribed by a rheumatologist.

**Psoriatic Arthritis**

- For the treatment of patients with active psoriatic arthritis who have not responded to an adequate trial with two disease modifying antirheumatic drugs (DMARDs) or who have an intolerance or contraindication to DMARDs.

Claim Note:

- Must be prescribed by a rheumatologist.

**Rheumatoid Arthritis**

- For patients with moderate to severe active rheumatoid arthritis who:
  - Have not responded to, or have had intolerable side-effects with, an adequate trial of combination therapy of at least two traditional DMARDs (disease modifying antirheumatic drugs). Combination DMARD therapy must include methotrexate unless contraindicated or not tolerated,
  - OR
  - Are not candidates for combination DMARD therapy must have had adequate trial of at least three traditional DMARDs in sequence, one of which must have been methotrexate unless contraindicated

Claim Note:

- Must be prescribed by a rheumatologist.

**Plaque Psoriasis**

- Requests will be considered for treatment of patients with severe, debilitating chronic plaque psoriasis who meet all of the following criteria:
  - Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genital region;
  - Failure to respond to, contraindications to or intolerance to methotrexate and cyclosporine;
  - Failure to respond to, intolerance to or unable to access phototherapy

Clinical Notes:

1. Continuation of therapy beyond 12 weeks will be based on response. Patients not responding adequately at these time points should have treatment discontinued with no further treatment with the same agent recommended.
2. An adequate response is defined as either:
  - ≥75% reduction in the Psoriasis Area and Severity Index (PASI) score from when treatment started (PASI 75),
  - OR
  - ≥50% reduction in the PASI score (PASI 50) with a ≥5 point improvement in the Dermatology Life Quality Index (DLQI) from when treatment started,
  - OR
  - A quantitative reduction in BSA affected with qualitative consideration of specific regions such as face, hands, feet, or genital region.
3. Concurrent use of >1 biologic will not be approved

Claim Notes:

- Initial approval limited to 12 weeks.
- Must be prescribed by a dermatologist
- Approval limited to a dose of 50 mg twice weekly for an initial 12 weeks, then 50 mg weekly, thereafter up to a year (if response criteria met at 12 weeks)

**ETIDRONATE (DIDRONEL and generic brands)  
200mg tablets**

See criteria under [Osteoporosis Drugs](#).

**ETIDRONATE AND CALCIUM (generic brands)  
400mg /500mg**

See criteria under [Osteoporosis Drugs](#).

**ETONOGESTREL / ETHINYL ESTRADIOL (NUVARING)  
11.4mg /2.6mg vaginal ring**

For conception control in women who are unable to take oral contraceptives.

**ETRAVIRINE (INTELENCE)  
100mg and 200mg tablets**

For the treatment of HIV-1 infection in patients who are antiretroviral experienced and have virologic failure due to HIV-1 strains resistant to multiple antiretroviral agents, including other non-nucleoside reverse transcriptase inhibitors.

**EVEROLIMUS (AFINITOR)  
2.5mg, 5mg, 10mg tablets**

1. For the treatment of metastatic renal cell carcinoma (mRCC) with clear cell morphology, in patients previously treated with a tyrosine kinase inhibitor.
2. In combination with exemestane, for the treatment of hormone-receptor positive, HER2 negative advanced breast cancer, in postmenopausal women with ECOG performance status  $\leq 2$  after recurrence or progression following a non-steroidal aromatase inhibitor (NSAI), if the treating oncologist would consider using exemestane.
3. For the treatment of patients with progressive, unresectable, well or moderately differentiated, locally advanced or metastatic pancreatic neuroendocrine tumours (pNET) with good performance status (ECOG 0-2), until disease progression.

Claim Note:

- Dosing for above indications: maximum 10mg daily

**EZETIMIBE (EZETROL and generic brands)  
10mg tablet**

For the treatment of hypercholesterolemia

- As adjunctive therapy with a statin, in patients who have not reached treatment goals on maximum tolerated statin therapy alone,  
OR
- As monotherapy in patients who are intolerant to statins and, when appropriate, fibrates.

**FEBUXOSTAT (ULORIC)  
80mg tablet**

For patients with symptomatic gout who have documented hypersensitivity to allopurinol. Hypersensitivity to allopurinol is a rare condition that is characterized by a major skin manifestation, fever, multi-organ involvement, lymphadenopathy and hematological abnormalities (eosinophilia, atypical lymphocytes).

Clinical Note:

- Intolerance or lack of response to allopurinol will not be covered by these criteria.

**FENTANYL (DURAGESIC MAT and generic brands)  
Transdermal system 12mcg/hr, 25mcg/hr, 50mcg/hr, 75mcg/hr and 100mcg/hr**

For the management of malignant or chronic non-malignant pain in adult patients;

- who were previously receiving continuous opioid administration (i.e. not opioid naive),  
OR
- who are unable to take oral therapy.

**FERUMOXYTOL (FERAHEME)  
30mg/mL (510mg/17mL) intravenous injection**

For the treatment of iron deficiency anemia in patients with chronic kidney disease who are predialysis or receiving home hemodialysis or peritoneal dialysis.

Claim Notes:

- Requests will be considered from a practitioner with a specialty in nephrology.
- The maximum dose that will be reimbursed is 510mg.

**FESOTERODINE FUMARATE (TOVIAZ)  
4mg, 8mg extended-release tablets**

- For the treatment of overactive bladder with symptoms of urgency, urgency incontinence, and urinary frequency, in patients who have not tolerated a reasonable trial of immediate-release oxybutynin.

Clinical Note:

- Requests for the treatment of stress incontinence will not be considered.

Claim Note:

- If the patient has had a claim for oxybutynin in the previous 24 months, the adjudication system will recognize this information and the claim for fesoterodine fumarate will be automatically reimbursed without the need for a written special authorization request.

**FIDAXOMICIN (DIFICID)  
200mg tablet**

For the treatment of Clostridium Difficile Infection (CDI) where the patient:

- has experienced a third or subsequent episode within 6 months of treatment with vancomycin for prior episode(s), with no previous trial of fidaxomicin;  
OR
- has experienced treatment failure\* with oral vancomycin for the current CDI episode;  
OR
- has had a documented allergy (immune-mediated reaction) to oral vancomycin;  
OR
- has experienced a severe adverse reaction or intolerance\*\* to oral vancomycin treatment that resulted in the discontinuation of vancomycin therapy.

Re-treatment criteria:

- Re-treatment with fidaxomicin will only be considered for an early relapse occurring within 30 days of the completion of the most recent fidaxomicin course.
- Relapse/recurrence occurring beyond 30 days after the completion of the most recent fidaxomicin course will require a trial with vancomycin, unless there is a documented allergy, severe adverse reaction or intolerance to prior oral vancomycin use.

Clinical Notes:

1. \*Treatment failure is defined as 7 days of vancomycin therapy without acceptable clinical improvement.
2. \*\*Details of severe adverse reaction or intolerance must be provided and should be clinically related to oral administration of vancomycin.

Claim Note:

- Requests will be approved for 200mg twice a day for 10 days.

**FILGRASTIM (NEUPOGEN - AMGEN)  
300mcg/1mL and 480mcg/1.6mL injections**

**CHEMOTHERAPY SUPPORT**

- Primary prophylaxis:  
When given as an integral part of an aggressive chemotherapy regimen with curative intent, in order to maintain dose intensity in compressed interval or dose dense treatment, as specified in a chemotherapy protocol.
- Secondary prophylaxis:
  - For use in patients receiving myelosuppressive chemotherapy who have experienced an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or
  - For use in patients who have experienced a dose reduction or treatment delay longer than one week, due to neutropenia.

- Dosing for Chemotherapy support:  
The manufacturer recommends an initial dose of 5mcg/kg/day. When dose scavenging techniques are not available, the following recommendations are suggested:
  - Patients ≤70 Kg use 1 mL vial (300mcg) DIN 01968017
  - Patients > 70 Kg use 1.6 mL vial (480mcg) PIN 00999001

#### **NON-MALIGNANT INDICATIONS**

- Treatment of congenital neutropenia, idiopathic neutropenia or cyclic neutropenia in patients with recurrent clinical infections.
- Drug-induced neutropenia (e.g. antiviral therapy in patients with HIV).
- Refer to product monograph for dosing recommendations.

#### **STEM-CELL TRANSPLANTATION**

- Mobilization:  
As an adjunct to progenitor cell transplantation, for mobilization of peripheral blood stem cells (PBSC). The recommended dosage is 10mcg/kg/day.
- Reconstitution/Engraftment:  
Post bone marrow transplantation (BMT) or PBSC transplantation to speed hematopoietic reconstitution. The recommended dosage is 5mcg/kg/day.

#### **UNACCEPTABLE USE**

- Treatment of febrile neutropenia or in the prevention of febrile neutropenia in the palliative setting.

#### Claim Note:

- Filgrastim must be prescribed or requested by a certified hematologist or medical oncologist.

#### **FINGOLIMOD (GILENYA) 0.5 mg capsule**

For the treatment of patients with Relapsing Remitting Multiple Sclerosis (RRMS) who meet all of the following criteria:

- Failure to respond to full and adequate courses<sup>1</sup> of at least one interferon OR glatiramer acetate; OR documented intolerance<sup>2</sup> to both therapies
- Have experienced one or more clinically disabling relapses in the previous year
- Demonstrate a significant increase in T2 lesion load compared with that from a previous MRI scan (i.e. 3 or more new lesions) OR have at least one gadolinium enhancing lesion
- Request is being made by and followed by a neurologist experienced in the management of RRMS
- Patient has a recent Expanded Disability Status Scale (EDSS) score less than or equal to 5.5 (i.e. patients must be able to ambulate at least 100 meters without assistance)

#### **Exclusion Criteria:**

- Combination therapy of fingolimod with other disease modifying therapies (e.g. Avonex, Betaseron, Copaxone, Rebif, Extavia, Tysabri) will not be funded.
- Combination therapy of fingolimod with Fampyra will not be funded.
- Patients with EDSS > 5.5 will not be funded
- Patients who have experienced a heart attack or stroke within the 6 months prior to the funding request will not be considered.
- Patients with a history of sick sinus syndrome, atrioventricular block, significant QT prolongation, bradycardia, ischemic heart disease, or congestive heart failure will not be considered.
- Patients younger than 18 years of age will not be considered.
- Patients with needle phobia or those having a preference for an oral therapy over an injection and who do not have one or more clinical contraindications to interferon or glatiramer therapy will not be funded.
- Skin reactions at the site of the injection do NOT qualify as a contraindication to interferon or glatiramer therapy.

#### **Requirements for Initial Requests:**

- The patient's physician must provide documentation setting out the details of the patient's most recent neurological examination within ninety (90) days of the submitted request. This must include a description of any recent attacks, the dates, and the neurological findings.

Renewal requests will be considered.

- Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within that last 90 days);  
**AND**
- Patient must be stable or have experienced no more than 1 disabling attack/relapse in the past year;

AND

- The recent Expanded Disability Status Scale (EDSS) score must be less than or equal to 5.5 (i.e. patients must be able to ambulate at least 100 meters without assistance)

Clinical Notes:

1. <sup>1</sup>Failure to respond to full and adequate courses is defined as a trial of at least 6 months of interferon or glatiramer therapy **AND** experienced at least one disabling relapse (attack) while on interferon or glatiramer therapy (MRI report does not need to be submitted with the request)
2. <sup>2</sup>Intolerance is defined as documented serious adverse effects or contraindications that are incompatible with further use of that class of drug. (Note that skin reactions at the site of the injection do NOT qualify as a contraindication to interferon or glatiramer therapy.)

Claim Notes:

- Dosage: 0.5 mg once daily
- Initial approval period: 1 year
- Renewal approval period: 2 years

**FLUDARABINE (FLUDARA)  
10mg tablet**

For the first-line treatment of chronic lymphocytic leukemia (CLL) in combination with rituximab (with or without cyclophosphamide).

**FORMOTEROL (FORADIL)  
12 mcg dry powder for inhalation**

**Reversible obstructive airway disease:**

- For the treatment of patients, 12 years of age or older, with reversible obstructive airway disease who are using optimal corticosteroid treatment, but are still poorly controlled.

**Chronic Obstructive Pulmonary Disease**

- For the treatment of chronic obstructive pulmonary disease (COPD) if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).
- Coverage can be provided without a trial of short-acting agent if there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1 /FVC ratio < 0.7) and significant symptoms (i.e. Medical Research Council (MRC) Dyspnea Scale score of 3-5).
- Combination therapy with tiotropium **AND** a long-acting beta2-adrenergic agonist/inhaled corticosteroid (LABA/ICS) will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms i.e. MRC score of 3-5)
  - AND there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids.

Clinical Note:

- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale). Spirometry reports from any point in time will be accepted.

Medical Research Council (MRC) Dyspnea Scale

COPD Stage	Symptoms
MODERATE – MRC 3 to 4	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
SEVERE – MRC 5	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

Claim Note:

- Prescriptions written by certified New Brunswick respirologists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

**FORMOTEROL (OXEZE)**  
**6 mcg and 12 mcg turbuhalers**

**Reversible obstructive airway disease:**

- For the treatment of patients, 12 years of age or older, with reversible obstructive airway disease who are using optimal corticosteroid treatment, but are still poorly controlled.

**Chronic Obstructive Pulmonary Disease**

- For the treatment of chronic obstructive pulmonary disease (COPD) if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).
- Coverage can be provided without a trial of short-acting agent if there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1 /FVC ratio < 0.7) and significant symptoms (i.e. Medical Research Council (MRC) Dyspnea Scale score of 3-5).
- Combination therapy with tiotropium AND a long-acting beta2-adrenergic agonist/inhaled corticosteroid (LABA/ICS) will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms i.e. MRC score of 3-5)
  - AND**
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids.

Clinical Note:

- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale). Spirometry reports from any point in time will be accepted.

Medical Research Council (MRC) Dyspnea Scale

COPD Stage	Symptoms
MODERATE – MRC 3 to 4	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
SEVERE – MRC 5	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

Claim Note:

- Prescriptions written by certified New Brunswick respirologists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

**FOSFOMYCIN (MONUROL)**  
**3g sachet**

For the treatment of uncomplicated urinary tract infections in adult female patients where:

- The infecting organism is resistant to other oral agents,
- OR**
- Other less costly agents are not tolerated.

Clinical Note:

- Fosfomycin is not indicated in the treatment of pyelonephritis or perinephric abscess.

**GALANTAMINE (REMINYL ER and generic brands)**  
**8mg, 16mg, and 24mg capsules**

See criteria under [Cholinesterase Inhibitors](#).

**GLATIRAMER ACETATE (COPAXONE)**  
**20mg injection**

1. For the treatment of patients with clinically definite multiple sclerosis (CDMS) including relapsing-remitting multiple sclerosis or secondary progressive multiple sclerosis who meet the following criteria:
  - Two disabling attacks of MS in the previous two years,
  - AND**
  - Ambulatory with or without aid (EDSS of less than or equal to 6.5)
2. For the treatment of patients who have experienced a clinically isolated syndrome (CIS) and are considered at risk for developing CDMS.



Clinical Note:

- An attack is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 24 hours in the absence of fever, and preceded by stability for at least one month.

Claim Note:

- Prescriptions written by New Brunswick neurologists do not require special authorization.

**GLYCOPYRRONIUM BROMIDE (SEEBRI BREEZHALER)  
50mcg capsule**

**Chronic Obstructive Pulmonary Disease**

- For the treatment of chronic obstructive pulmonary disease (COPD) if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).
- Coverage can be provided without a trial of short-acting agent if there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1 /FVC ratio < 0.7) and significant symptoms (i.e. Medical Research Council (MRC) Dyspnea Scale score of 3-5).
- Combination therapy with glycopyrronium bromide AND a long-acting beta2-adrenergic agonist/inhaled corticosteroid (LABA/ICS) will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (i.e. MRC score of 3-5)  
**AND**
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids.

Clinical Note:

- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale). Spirometry reports from any point in time will be accepted.

Medical Research Council (MRC) Dyspnea Scale

COPD Stage	Symptoms
MODERATE – MRC 3 to 4	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
SEVERE – MRC 5	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

**GOLIMUMAB (SIMPONI)  
50mg/0.5mL autoinjector/pre-filled syringe**

1. For the treatment of patients with moderate to severe ankylosing spondylitis (e.g. Bath AS Disease Activity Index (BASDAI) score ≥ 4 on 10 point scale) who:
  - Have axial symptoms\* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum 3 month observation period or in whom NSAIDs are contraindicated  
**OR**
  - Have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum 3 month observation period and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Renewal requests:

- Requests for continuation of therapy must include information showing the clinical beneficial effects of the treatment, specifically:
  - a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score  
**OR**
  - patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or “ability to return to work”)

Clinical Notes:

1. Golimumab will not be reimbursed in combination with other anti-TNF agents.
2. \* Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
  - Initial approval will be for 4 x 50 mg doses in a 4 month period.
  - Approvals for continuation of therapy will be for 12 x 50 mg doses annually with no dose escalation permitted.
2. For the treatment of moderate to severe psoriatic arthritis in patients who:
- Have at least three active and tender joints,  
AND
  - Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Renewal Requests:

- Requests for continuation of therapy must include information demonstrating clinical beneficial effects of the treatment.

Clinical Note:

- Golimumab will not be reimbursed in combination with other anti-TNF agents.

Claim Notes:

- Must be prescribed by a rheumatologist or internist
  - Initial approval will be for 4 x 50mg doses in a 4 month period.
  - Approvals for continuation of therapy will be for 12 x 50 mg doses annually with no dose escalation permitted.
3. For patients with moderate to severe active rheumatoid arthritis who:
- Have not responded to, or have had intolerable side-effects with, an adequate trial of combination therapy of at least two traditional DMARDs (disease modifying antirheumatic drugs). Combination DMARD therapy must include methotrexate unless contraindicated or not tolerated,  
OR
  - Are not candidates for combination DMARD therapy must have had adequate trial of at least three traditional DMARDs in sequence, one of which must have been methotrexate unless contraindicated.

Renewal Requests:

- Requests for continuation of therapy must include information demonstrating clinical beneficial effects of the treatment.

Clinical Note:

- Golimumab will not be reimbursed in combination with anti-TNF agents.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Initial approval will be for 4 x 50 mg doses in a 4 month period.
- Approvals for continuation of therapy will be for 12 x 50 mg doses annually with no dose escalation permitted.

**GRANISETRON (KYTRIL and generic brand)  
1mg tablet**

For the treatment of emesis in patients who are:

- receiving moderately or severely emetogenic chemotherapy  
OR
- receiving intravenous chemotherapy or radiotherapy and who have not experienced adequate control with other available antiemetics  
OR
- receiving any intravenous chemotherapy or radiotherapy and have experienced emesis with a prior cycle of chemotherapy with intolerable side effects to other antiemetics, including steroids and anti-dopaminergic agents.

Clinical Notes:

1. Only requests for the oral dosage forms are eligible for consideration. Usually a single oral dose pre-chemotherapy is sufficient to control symptoms.
2. Some patients may require additional therapy up to 48 hours after the last dose of chemotherapy or last radiation treatment. Benefit beyond 48 hours has not been established.
3. When used in combination with aprepitant, only a single oral dose pre-chemotherapy will be covered.

Claim Note:

- Prescription claims for up to a maximum of 12 tablets of ondansetron or 2 tablets of granisetron will be automatically reimbursed every 28 days when the prescription is written by an oncologist or an oncology clinical associate/general practitioners-oncology. If additional medication is required within a 28 day period subsequent to the initial prescription, a request should be made through special authorization.

**GRASS POLLEN ALLERGEN EXTRACT (ORALAIR)  
100IR and 300IR sublingual tablets**

For the seasonal treatment of grass pollen allergic rhinitis in patients who have not adequately responded to, or tolerated, conventional pharmacotherapy.

Clinical Notes:

- Treatment with grass pollen allergen extract must be initiated by physicians with adequate training and experience in the treatment of respiratory allergic diseases.
- Treatment should be initiated four months before the onset of pollen season and should only be continued until the end of the season
- Treatment should not be taken for more than three consecutive years

**Hp-PAC (Containing LANSOPRAZOLE 30mg Cap, AMOXICILLIN 500mg Cap, CLARITHROMYCIN 500mg Tab)**

For the treatment of patients with *H. pylori* infection and active duodenal ulcer disease.

Clinical Notes:

1. Treatment should be limited to a period of 7 days for first-line therapy.
2. In cases of *H. pylori* treatment failure or re-infection, second-line treatment should be limited to a period of 7-14 days provided at least 4 weeks have elapsed from first-line treatment. In addition, if treatment failure or re-infection occurs within a three month period of first-line treatment, a different antibiotic should be used.

**IBRUTINIB (IMBRUVICA)  
140mg capsule**

For the treatment of patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy and are considered inappropriate for treatment or retreatment with a fludarabine-based regimen.

**IMATINIB (GLEEVEC and generic brands)  
100mg and 400mg tablets**

Requests from specialists in hematology/oncology will be considered for:

1. Patients who have documented evidence of Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML), with an ECOG performance status of 0-2\*.
2. Patients with C-Kit positive (CD117), metastatic or locally advanced, inoperable gastrointestinal stromal tumours (GIST), who have an ECOG performance status of 0-2\*.
3. For the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL) when used as a single agent for induction and maintenance phase therapy.

Clinical Note:

- \*Patients who are asymptomatic and those who are symptomatic and in bed less than 50% of the time.

**IMIQUIMOD (ALDARA and generic brand)  
5% cream**

1. For the treatment of external genital and external perianal/condyloma acuminata warts.

Claim Note:

- Approval Period: 16 weeks

2. For the treatment of actinic keratosis in patients who have failed treatment with 5-Fluorouracil (5-FU) and cryotherapy.

Claim Note:

- Approval Period: 16 weeks

3. For the treatment of biopsy-confirmed primary superficial basal cell carcinoma:

- with a tumour diameter of  $\leq 2$  cm

AND

- located on the trunk, neck or extremities (excluding hands and feet)

AND

- where surgery or irradiation therapy is not medically indicated
  - recurrent lesions in previously irradiated area

OR

- multiple lesions, too numerous to irradiate or remove surgically.

Clinical Note:

- Surgical management should be considered first-line for superficial basal cell carcinoma in most patients, especially for isolated lesions.

Claim Note:

- Approval Period: 6 weeks

**INCOBOTULINUMTOXIN-A (XEOMIN)  
50 LD<sub>50</sub> units/ vial and 100 unit vial for injection**

- For the treatment of blepharospasm in patients 18 years of age and older.
- For the treatment of cervical dystonia (spasmodic torticollis) in patients 18 years of age or older.

**INDACATEROL MALEATE (ONBREZ BREEZHALER)  
75mcg inhalation powder hard capsules**

**Chronic Obstructive Pulmonary Disease**

- For the treatment of chronic obstructive pulmonary disease (COPD) if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).
- Coverage can be provided without a trial of short-acting agent if there is spirometric evidence of at least moderate to severe airflow obstruction (FEV<sub>1</sub> < 60% and FEV<sub>1</sub> /FVC ratio < 0.7) and significant symptoms (i.e. Medical Research Council (MRC) Dyspnea Scale score of 3-5).
- Combination therapy with tiotropium AND a long-acting beta2-adrenergic agonist/inhaled corticosteroid (LABA/ICS) will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (FEV<sub>1</sub> < 60% and FEV<sub>1</sub>/FVC ratio < 0.7), and significant symptoms i.e. MRC score of 3-5)  
**AND**
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids.

Clinical Notes:

- Dose not to exceed 75 mcg/day.
- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale). Spirometry reports from any point in time will be accepted.

Medical Research Council (MRC) Dyspnea Scale

COPD Stage	Symptoms
MODERATE – MRC 3 to 4	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
SEVERE – MRC 5	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

Claim Note:

- Prescriptions written by certified New Brunswick respirologists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

**INDACATEROL / GLYCOPYRROLATE (ULTIBRO BREEZEHALER)  
110mcg / 50mcg powder for inhalation**

For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients with an inadequate response to a long-acting beta-2 agonist (LABA) or long-acting anticholinergic (LAAC).

Clinical notes:

- Moderate to severe COPD is defined by spirometry (post-bronchodilator) FEV<sub>1</sub> < 60% predicted and FEV<sub>1</sub>/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted.

If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e. Medical Research Council (MRC) Dyspnea Scale score of at least Grade 3). MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath (SOB) from COPD or has to stop for breath when walking at own pace on the level.

- Inadequate response is defined as persistent symptoms after at least 2 months of long-acting beta-2 agonist (LABA) or long-acting anticholinergic therapy (LAAC).

**INFLIXIMAB (REMICADE)  
100mg liquid injection**

**Ankylosing Spondylitis**

- For the treatment of patients with moderate to severe ankylosing spondylitis (e.g. Bath AS Disease Activity Index (BASDAI) score  $\geq 4$  on 10 point scale) who:
  - have axial symptoms\* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation or in whom NSAIDs are contraindicated
  - OR
  - have peripheral symptoms and who have failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

**Renewal Requests:**

- Requests for renewal must include information showing the beneficial effects of the treatment, specifically:
  - a decrease of at least 2 points on the BASDAI scale, compared with the pre-treatment score;
  - OR
  - patient and expert opinion of an adequate clinical response as indicated by a significant functional improvement (measured by outcomes such as HAQ or "ability to return to work")

Clinical Notes:

1. Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease, do not require a trial of NSAIDs alone
2. Infliximab will not be reimbursed in combination with other anti-TNF agents.

Claim Notes:

- Must be prescribed by a rheumatologist or internist
- Approval will be for a maximum of 6 months
- Approvals will be for a maximum of 5mg/kg at weeks 0, 2 and 6, then every 6 to 8 weeks thereafter.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**Crohn's Disease**

- For moderately to severely active Crohn's disease in patients who are refractory or have contraindications to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy. Initial approval will consist of 3 doses of 5 mg/kg given at weeks 0, 2 and 6.

Clinical Note:

- Infliximab will not be reimbursed in combination with other anti-TNF agents.

Claim Notes:

- Ongoing coverage for maintenance therapy will only be reimbursed for responders and for a dose not exceeding 5mg/kg every 8 weeks. Coverage must be reassessed annually and is dependent on evidence of continued response.
- Must be prescribed by, or in consultation with, a gastroenterologist or physician with a specialty in gastroenterology.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**Plaque Psoriasis**

- Requests will be considered for treatment of patients with severe, debilitating chronic plaque psoriasis who meet all of the following criteria:
  - Body surface area (BSA) involvement of  $>10\%$  and/or significant involvement of the face, hands, feet or genital region;
  - Failure to respond to, contraindications to or intolerance to methotrexate and cyclosporine;
  - Failure to respond to, intolerance to or unable to access phototherapy

Clinical Notes:

1. Continuation of therapy beyond 12 weeks will be based on response. Patients not responding adequately at these time points should have treatment discontinued with no further treatment with the same agent recommended.
2. An adequate response is defined as either:
  - $\geq 75\%$  reduction in the Psoriasis Area and Severity Index (PASI) score from when treatment started (PASI 75),
  - OR
  - $\geq 50\%$  reduction in the PASI score (PASI 50) with a  $\geq 5$  point improvement in the Dermatology Life Quality Index (DLQI) from when treatment started,

OR

- A quantitative reduction in BSA affected with qualitative consideration of specific regions such as face, hands, feet, or genital region.

3. Concurrent use of >1 biologic will not be approved

Claim Notes:

- Initial approval limited to 12 weeks.
- Must be prescribed by a dermatologist
- Approval limited to a dose of 5 mg/kg administered at 0, 2, and 6 weeks, then every 8 weeks up to a year (if response criteria met at 12 weeks)
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**Rheumatoid Arthritis**

- For patients with moderate to severe active rheumatoid arthritis who:
    - Have not responded to, or have had intolerable side-effects with, an adequate trial of combination therapy of at least two traditional DMARDs (disease modifying antirheumatic drugs). Combination DMARD therapy must include methotrexate unless contraindicated or not tolerated,
- OR
- Are not candidates for combination DMARD therapy must have had adequate trial of at least three traditional DMARDs in sequence, one of which must have been methotrexate unless contraindicated

Claim Note:

- Must be prescribed by a rheumatologist.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**INSULIN ASPART (NOVORAPID)  
10mL vials and 5x3mL cartridges**

For patients with type I or II diabetes who have experienced frequent episodes of postprandial hypoglycemia; have unpredictable mealtimes; have insulin resistance; or who are using continuous subcutaneous insulin infusion.

Claim Note:

- Prescriptions written by New Brunswick endocrinologists and internists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

**INSULIN DETEMIR (LEVEMIR PENFILL)  
100 U/mL cartridge**

For the treatment of patients who have been diagnosed with Type 1 or Type 2 diabetes requiring insulin and have previously taken insulin NPH and/or pre-mix daily at optimal dosing.

AND

1. Have experienced unexplained nocturnal hypoglycemia at least once a month despite optimal management.
- OR
2. Have documented severe or continuing systemic or local allergic reaction to existing insulin(s).

Claim Note:

- Requests should be submitted on the long-acting insulin analogue special authorization request form.

**INSULIN GLARGINE (LANTUS)  
100U/mL vial, cartridge, and SoloSTAR**

For the treatment of patients who have been diagnosed with Type 1 or Type 2 diabetes requiring insulin and have previously taken insulin NPH and/or pre-mix daily at optimal dosing.

AND

1. Have experienced unexplained nocturnal hypoglycemia at least once a month despite optimal management.
- OR
2. Have documented severe or continuing systemic or local allergic reaction to existing insulin(s).

Claim Note:

- Requests should be submitted on the long-acting insulin analogue special authorization request form.

**INSULIN GLULISINE (APIDRA)  
100IU/mL vials, cartridges and SoloSTAR pre-filled pens**

For patients with type I or II diabetes who have experienced frequent episodes of postprandial hypoglycemia; have unpredictable mealtimes; have insulin resistance; or who are using continuous subcutaneous insulin infusion.

Claim Notes:

- Prescriptions written by New Brunswick endocrinologists and internists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.
- Insulin glulisine is a regular benefit for Plan D≤18 years of age.

**INSULIN LISPRO (HUMALOG)  
10mL vials, 1.5mL and 3mL cartridges, and KwikPen pre-filled pen**

For patients with type I or II diabetes who have experienced frequent episodes of postprandial hypoglycemia; have unpredictable mealtimes; have insulin resistance; or who are using continuous subcutaneous insulin infusion.

Claim Note:

- Prescriptions written by New Brunswick endocrinologists and internists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

**INTERFERON BETA-1A (AVONEX PS)  
30mcg/0.5mL injections  
INTERFERON BETA-1A (REBIF)  
22mcg/0.5mL, 44mcg/0.5mL, 66mcg/1.5mL, 132mcg/1.5mL injections  
INTERFERON BETA-1B (BETASERON, EXTAVIA)  
0.3mg injection**

1. For the treatment of patients with clinically definite multiple sclerosis (CDMS) including relapsing-remitting multiple sclerosis, secondary progressive multiple sclerosis or relapsing progressive multiple sclerosis who meet the following criteria:
  - Two disabling attacks of MS in the previous two years,  
AND
  - Ambulatory with or without aid (EDSS of less than or equal to 6.5)
2. For the treatment of patients who have experienced a clinically isolated syndrome (CIS) and are considered at risk for developing CDMS.

Clinical Note:

- An attack is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 24 hours in the absence of fever, and preceded by stability for at least one month.

Claim Note:

- Prescriptions written by New Brunswick neurologists do not require special authorization.

**IRON DEXTRAN (DEXIRON)  
50mg/mL injection**

For the treatment of iron deficiency anemia in patients who

- are intolerant to oral iron replacement products,  
OR
- have not responded to adequate therapy with oral iron.

**IRON SUCROSE (VENOFER)  
20mg/mL injection**

For the treatment of iron deficiency anemia in patients who

- are intolerant to oral iron replacement products,  
OR
- have not responded to adequate therapy with oral iron.

**ITRACONAZOLE (SPORANOX)  
100mg capsule**

1. For the treatment of severe systemic fungal infections not responding to alternative therapy.
2. For the treatment of severe or resistant fungal infections in immunocompromised patients not responding to alternative therapy.
3. For the treatment of skin infections (excluding onychomycosis) caused by dermatophyte fungi not responding to alternative therapy.

**IVACAFTOR (KALYDECO)  
150mg tablet**

For the treatment of cystic fibrosis in patients who meet the following criteria:

- age 6 years and older; and
- have documented G551D mutation in the Cystic Fibrosis Transmembrane conductance Regulator (CFTR) gene.

**Initial renewal criteria:**

Renewal requests will be considered in patients with documented response to treatment (after at least 6 months of therapy) as evidenced by the following:

In cases where the patient's sweat chloride levels prior to commencing therapy were above 60mmol/litre:

- the patient's sweat chloride level fell below 60mmol/litre; or
- the patient's sweat chloride level is 30% lower than the level reported in a previous test;

In cases where the baseline sweat chloride levels prior to commencing therapy were below 60mmol/litre:

- the patient's sweat chloride level is 30% lower than the level reported in a previous test; or
- the patient demonstrates a sustained absolute improvement in FEV1 of at least 5% when compared to the FEV1 test conducted prior to the commencement of therapy.

**Subsequent renewal criteria:**

- The patient is continuing to benefit from therapy.

Clinical Notes:

- The patient's sweat chloride level and FEV1 must be provided with each request.
- A sweat chloride test must be performed within a few months of starting ivacaftor therapy to determine if sweat chloride levels are reducing.
  - If the expected reduction occurs, a sweat chloride test must be performed again 6 months after starting therapy to determine if the full reduction has been achieved. Thereafter, sweat chloride levels must be checked annually.
  - If the expected reduction does not occur, a sweat chloride test should be performed again one week later. If the criteria are not met, funding will be discontinued.

Claim Notes:

- Approved dose: 150mg every 12 hours
- Initial and renewal approval duration: 1 year
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**LACOSAMIDE (VIMPAT)  
50mg, 100mg, 150mg and 200mg tablets**

For the adjunctive treatment of refractory partial-onset seizures in patients who meet all of the following criteria:

- are under the care of a physician experienced in the treatment of epilepsy,  
AND
- are currently receiving two or more antiepileptic drugs,  
AND
- in whom all other antiepileptic drugs are ineffective or not appropriate

**LACTULOSE (various brands)  
667 mg/mL syrup**

For the treatment of hepatic encephalopathy in patients with liver disease.

Clinical Note:

- Please note requests for treatment of constipation will not be considered.

**LANREOTIDE ACETATE (SOMATULINE AUTOGEL)  
60mg/0.3mL, 90mg/0.3mL and 120mg/0.5mL pre-filled syringes**

For the treatment of acromegaly.



**LANSOPRAZOLE (PREVACID and generic brands)  
15mg and 30mg capsules**

See criteria under [Proton Pump Inhibitors](#).

**LANSOPRAZOLE (PREVACID FASTAB)  
15mg and 30mg delayed release tablets**

For patients who meet the special authorization criteria for a [proton pump inhibitor](#) and require administration through a feeding tube.

**LAPATINIB (TYKERB)  
250mg tablet**

For use in combination with capecitabine, for the treatment of HER2-positive patients with advanced or metastatic breast cancer who have progressed on trastuzumab-based treatments (e.g. taxanes, anthracycline, trastuzumab) and who have an ECOG performance status of 0-2.

Renewal criteria:

- Written confirmation that the patient has responded to treatment and that there is no evidence of disease progression.

Clinical Note:

- Requests will not be considered for use in combination with trastuzumab for second-line HER2-positive metastatic breast cancer or in the adjuvant setting

Claim Notes:

- Initial approval period: 6 months
- Renewal period: 6 months

**LENALIDOMIDE (REVLIMID)  
5mg, 10mg, 15mg and 25mg capsules**

1. For the treatment of Myelodysplastic Syndrome (MDS) in patients with:
  - Demonstrated diagnosis of MDS on bone marrow aspiration
  - Presence of 5-q deletion documented by appropriate genetic testing
  - International Prognostic Scoring System (IPSS) risk category low or intermediate-1<sup>†</sup>
  - Presence of symptomatic anemia (defined as transfusion dependent)\*

Renewal criteria:

- For patients who were transfusion-dependent and have demonstrated a reduction in transfusion requirements of at least 50%.
- Renewal requests for all other patients will be considered on a case-by-case basis. Information describing the results of serial CBC (pre- and post-lenalidomide) and any other objective evidence of response should be included.

Clinical Notes:

1. <sup>†</sup> calculator available on [www.uptodate.com](http://www.uptodate.com)
2. \*Requests for patients who are not transfusion-dependent will be considered on a case-by-case basis. The physician should provide clinical evidence of symptomatic anemia affecting the patient's quality of life and the rationale for why transfusions are not being used.

Claim Notes:

- Initial approval period: 6 months
  - Renewal period: 1 year
2. For the treatment of multiple myeloma when used in combination with dexamethasone, in patients who:
    - Are not candidates for autologous stem cell transplant;

AND

    - Where the patient is either:
      - Refractory to or has relapsed after the conclusion of initial or subsequent treatments and who is suitable for further chemotherapy;

OR

    - Has completed at least one full treatment regimen as initial therapy and is experiencing intolerance to their current chemotherapy.
  3. For the maintenance treatment of patients with newly diagnosed multiple myeloma, following autologous stem-cell transplantation (ASCT), who have stable disease or better, with no evidence of disease progression.

Renewal criteria:

- Written confirmation that there is no evidence of disease progression.

Clinical Notes:

- Recommended Dose: Initial dose of 10 mg daily. Dose adjustments (5-15 mg) may be necessary based on individual patient characteristics/responses.
- Lenalinomide may be continued until evidence of disease progression or development of unacceptable toxicity requiring discontinuation of lenalidomide.

Claim Notes:

- Initial approval duration: 1 year
- Renewal approval duration: 1 year

Clinical Note:

- Due to its structural similarities to thalidomide, lenalidomide (Revlimid) is only available through a controlled distribution program called RevAid<sup>®</sup> to minimize the risk of fetal exposure. Only prescribers and pharmacists registered with this program are able to prescribe and dispense lenalidomide (Revlimid). In addition, patients must be registered and meet all the conditions of the program in order to receive the product. For information, call 1-888-RevAid1 or log onto [www.RevAid.ca](http://www.RevAid.ca).

Claim Note:

- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

### **LEUPROLIDE (LUPRON) 5mg injection**

1. For the palliative treatment of stage D<sub>2</sub> carcinoma of the prostate.
2. For the treatment of central precocious puberty.

### **LEVETIRACETAM (KEPPRA and generic brands) 250mg, 500mg and 750mg tablets**

As an adjunctive therapy in the management of patients with epilepsy who are not satisfactorily controlled by conventional therapy.

### **LEVOCARNITINE (CARNITOR) 100mg/mL oral liquid and 330mg tablet**

1. For the treatment of patients with primary systemic carnitine deficiency.
2. For the treatment of patients with an inborn error of metabolism that results in secondary carnitine deficiency.

### **LEVODOPA / CARBIDOPA / ENTACAPONE (STALEVO) 50/12.5/200 mg, 75/18.75/200 mg, 100/25/200 mg, 125/31.25/200 mg, and 150/37.5/200 mg tablets**

For the treatment of patients with Parkinson's disease

- who are currently receiving immediate-release levodopa/carbidopa and entacapone,  
OR
- who are not well controlled and are experiencing significant "wearing off" symptoms despite optimal therapy with levodopa/decarboxylase.

### **LEVOFLOXACIN (LEVAQUIN and generic brands) 250mg and 500mg tablets**

- For the completion of therapy instituted in the hospital setting for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB).
- For the treatment of severe pneumonia in nursing home patients.
- For the treatment<sup>1</sup> of CAP in patients;
  - with co-morbidity<sup>2</sup> upon radiographic confirmation of pneumonia,  
OR
  - who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate).
- For the treatment<sup>1</sup> of AECB in complicated patients<sup>3</sup> who have failed treatment with one of the following (amoxicillin, doxycycline, TMP-SMX, cefuroxime, macrolide, ketolide or amoxicillin-clavulanate).

Clinical Notes:

1. If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.

2. <sup>2</sup> Co-morbidity includes chronic lung disease, malignancy, diabetes, liver, renal or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDS, smoking, malnutrition or acute weight loss.
3. <sup>3</sup> Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea
  - AND
  - FEV<sub>1</sub> < 50% predicted
  - OR
  - FEV<sub>1</sub> 50-65% and one of the following:
    - ≥ 4 exacerbations per year
    - Ischemic heart disease
    - Chronic oral steroid use
    - Antibiotic use in the past 3 months

Claim Notes:

- Prescriptions written by New Brunswick infectious disease specialists, medical microbiologists, medical oncologists, respirologists and internal medicine specialists will not require special authorization.

**LINAGLIPTIN (TRAJENTA)  
5mg tablets**

For patients with type 2 diabetes mellitus with inadequate glycemic control while on optimal doses of metformin and a sulfonylurea, and for whom NPH insulin is not an option, when added as a third agent.

**LINEZOLID (ZYVOXAM and generic brands)  
600mg tablets**

- For treatment of proven vancomycin-resistant *enterocci* (VRE) infections.
- For the treatment of proven methicillin-resistant *Staphylococcus aureus* (MRSA) / methicillin-resistant *Staphylococcus epidermidis* (MRSE) infections in patients who are unresponsive to, or intolerant of, intravenous vancomycin or in whom intravenous vancomycin is not appropriate.

Claim Note:

- The drug must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.

**LISDEXAMFETAMINE DIMESYLATE (VYVANSE)  
10mg, 20mg, 30mg, 40mg, 50mg, 60mg capsules**

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients age 6 to 25 years who:

- Demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning;
- AND
- Have been tried on methylphenidate (immediate release or long-acting formulation) or dexamphetamine with unsatisfactory results.

Claim Notes:

- Requests will be considered from specialists in pediatric psychiatry, pediatricians or general practitioners with expertise in ADHD.
- The maximum dose reimbursed is 60mg daily.

**LOW MOLECULAR WEIGHT HEPARINS (Dalteparin, Enoxaparin, Nadroparin, Tinzaparin).**

1. For the treatment of venous thromboembolism (VTE) and/or pulmonary embolism (PE) for a maximum of 30 days.
2. For the extended treatment of recurrent symptomatic venous thromboembolism (VTE) that has occurred while patients are on therapeutic doses of warfarin.
3. For the prophylaxis of venous thromboembolism (VTE) up to 35 days following elective hip replacement or hip fracture surgery.
4. For the prophylaxis of VTE up to 10 days following elective knee replacement surgery.
5. For the prophylaxis of venous thromboembolism (VTE) post abdominal or pelvic surgery for management of a malignant tumor for up to 28 days (enoxaparin only).
6. For the treatment and secondary prevention of symptomatic venous thromboembolism (VTE) or pulmonary embolism (PE) for a period of up to 6 months in patients with cancer for whom warfarin therapy is not an option.

**Claim Note:**

- An annual quantity limit of approximately 30 days of therapy is applied to all Low Molecular Weight Heparin DINs listed in the table. If the DIN does not appear in the table or if an additional quantity is required, a request must be made through special authorization.

Product Name	DIN	Approximate 30 Day Treatment Quantity
<u>Dalteparin (Fragmin)</u> <ul style="list-style-type: none"> <li>• 2,500IU/0.2mL pre-filled syringe</li> <li>• 3,500IU/0.28mL pre-filled syringe</li> <li>• 5,000IU/0.2mL pre-filled syringe</li> <li>• 7,500IU/0.3mL pre-filled syringe</li> <li>• 10,000IU/0.4mL pre-filled syringe</li> <li>• 12,500IU/0.5mL pre-filled syringe</li> <li>• 15,000IU/0.6mL pre-filled syringe</li> <li>• 18,000IU/0.72mL pre-filled syringe</li> <li>• 25,000IU/mL multi-dose vial</li> </ul>	02132621 02430789 02132648 02352648 02352656 02352664 02352672 02352680 02231171	0.2mL x 30 syringes = 6mL 0.28mL x 30 syringes = 8.4mL 0.2mL x 30 syringes = 6mL 0.3mL x 30 syringes = 9mL 0.4mL x 30 syringes = 12mL 0.5mL x 30 syringes = 15mL 0.6mL x 30 syringes = 18mL 0.72mL x 30 syringes = 21.6mL 3.8mL x 6 vials = 22.8mL
<u>Enoxaparin Lovenox &amp; Lovenox HP)</u> <ul style="list-style-type: none"> <li>• 30mg/0.3mL pre-filled syringe</li> <li>• 40mg/0.4mL pre-filled syringe</li> <li>• 60mg/0.6mL pre-filled syringe</li> <li>• 80mg/0.8mL pre-filled syringe</li> <li>• 100mg/mL pre-filled syringe</li> <li>• 120mg/0.8mL pre-filled syringe (HP)</li> <li>• 150mg/mL pre-filled syringe (HP)</li> </ul>	02012472 02236883 02378426 02378434 02378442 02242692 02378469	0.3mL x 30 syringes = 9mL 0.4mL x 30 syringes = 12mL 0.6mL x 30 syringes = 18mL 0.8mL x 30 syringes = 24mL 1mL x 30 syringes = 30mL 0.8mL x 30 syringes = 24mL 1mL x 30 syringes = 30mL
<u>Nadroparin (Fraxiparin &amp; Fraxiparin Forte)</u> <ul style="list-style-type: none"> <li>• 2,850IU/0.3mL pre-filled syringe</li> <li>• 3,800IU/0.4mL pre-filled syringe</li> <li>• 5,700IU/0.6mL pre-filled syringe</li> <li>• 7,600IU/0.8mL pre-filled syringe</li> <li>• 9,500IU/mL pre-filled syringe</li> <li>• 11,400IU/0.6mL pre-filled syringe</li> <li>• 15,200IU/0.8mL pre-filled syringe</li> <li>• 19,000IU/mL pre-filled syringe</li> </ul>	02236913     02240114	0.3mL x 30 syringes = 9mL 0.4mL x 30 syringes = 12mL 0.6mL x 30 syringes = 18mL 0.8mL x 30 syringes = 24mL 1mL x 30 syringes = 30mL 0.6mL x 30 syringes = 18mL 0.8mL x 30 syringes = 24mL 1.0mL x 30 syringes = 30mL
<u>Tinzaparin (Innohep)</u> <ul style="list-style-type: none"> <li>• 2,500IU/0.25mL pre-filled syringe</li> <li>• 3,500IU/0.35mL pre-filled syringe</li> <li>• 4,500IU/0.45mL pre-filled syringe</li> <li>• 8,000IU/0.4mL pre-filled syringe</li> <li>• 10,000IU/0.5mL pre-filled syringe</li> <li>• 12,000IU/0.6mL pre-filled syringe</li> <li>• 14,000IU/0.7mL pre-filled syringe</li> <li>• 16,000IU/0.8mL pre-filled syringe</li> <li>• 18,000IU/0.9mL pre-filled syringe</li> </ul>	02229755 02358158 02358166 02429462 02231478 02429470 02358174 02429489 02358182	0.25mL x 30 syringes = 7.5mL 0.35mL x 30 syringes = 10.5mL 0.45mL x 30 syringes = 13.5mL 0.4mL x 30 syringes = 12mL 0.5mL x 30 syringes = 15mL 0.6mL x 30 syringes = 18mL 0.7mL x 30 syringes = 21mL 0.8mL x 30 syringes = 24mL 0.9mL x 30 syringes = 27mL

**LURASIDONE (LATUDA)**  
**20mg, 40mg, 60mg, 80mg and 120mg film-coated tablets**

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients with a history of failure, intolerance, or contraindication to at least one less expensive antipsychotic agent.

**MARAVIROC (CELSENTRI)**  
**150mg and 300mg tablets**

For the treatment of HIV-1 infection in patients who have CCR5 tropic viruses and who have documented resistance to at least one agent from each of the three major classes of antiretrovirals (i.e. nucleoside/tide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors.)

Clinical Note:

- Requests for HIV-1 treatment-naïve patients will not be considered.

**METFORMIN / SAXAGLIPTIN (KOMBOGLYZE)**  
**500mg/2.5mg, 850mg/2.5mg, and 1000mg/2.5mg tablets**

For the treatment of type 2 diabetes mellitus in patients:

- for whom insulin is not an option
- AND
- who are already stabilized on therapy with metformin, a sulfonylurea and saxagliptin, to replace the individual components of saxagliptin and metformin.

**METHADONE**  
**Compounded Oral Solution**

Requests from New Brunswick physicians authorized to prescribe methadone will be considered:

1. For the treatment of severe cancer-related or chronic non-malignant pain as an alternative to other opioids.
2. For the treatment of opioid dependence.

All requests must meet requirements set out by the New Brunswick Drug Plans.

**Pharmacy Claims:**

Claims submitted by pharmacies must be billed using the applicable PIN.

Opioid dependence	00999734
Chronic pain	00999801

**METHADONE HCL (METHADOSE)**  
**10mg/mL dye-free, sugar-free, unflavored oral concentrate**

Requests from New Brunswick physicians authorized to prescribe methadone will be considered:

1. For the treatment of opioid dependence.

All requests must meet requirements set out by the New Brunswick Drug Plans.

**Pharmacy Claims:**

Claims submitted by pharmacies must be billed using DIN 02394618.

**METHADONE HCL (METADOL)**  
**1 mg/mL oral solution and 10 mg/mL oral concentrate**

Requests from New Brunswick physicians authorized to prescribe methadone will be considered:

1. For the treatment of severe cancer-related or chronic non-malignant pain as an alternative to other opioids.
2. For the treatment of opioid dependence.

All requests must meet requirements set out by the New Brunswick Drug Plans.

**Pharmacy Claims:**

Claims submitted by pharmacies must be billed using the applicable PIN.

1mg/mL oral solution	
Opioid dependence	00903823
Chronic pain	00903825

10mg/mL oral concentrate	
Opioid dependence	00903824
Chronic pain	00903826

**METHADONE HCL (METADOL)  
1mg, 5mg, 10mg and 25mg tablets**

Requests from New Brunswick physicians authorized to prescribe methadone will be considered:

1. For the treatment of severe cancer-related or chronic non-malignant pain as an alternative to other opioids.

Clinical Note:

- Requests will not be considered:
  1. For the treatment of opioid dependence.
  2. Preparations compounded using Metadol tablets will not be considered.

**METHYLPHENIDATE (BIPHENTIN)  
10mg, 15mg, 20mg, 30mg, 40mg, 50mg, 60mg and 80mg controlled release capsules**

For the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in children age 6 to 25 years who demonstrate significant symptoms and who have tried immediate release and slow release methylphenidate with unsatisfactory results.

Claim Note:

- Requests will be considered from specialists in pediatric psychiatry, pediatricians or general practitioners with expertise in ADHD.

**METHYLPHENIDATE-ER (CONCERTA and generic brands)  
18mg, 27mg, 36mg and 54mg extended-release tablets**

For the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in children aged 6 to 25 years who demonstrate significant symptoms and who have tried immediate release or slow release methylphenidate with unsatisfactory results.

Claim Note:

- Requests will be considered from specialists in pediatric psychiatry, pediatricians or general practitioners with expertise in ADHD.

**MIRABEGRON (MYRBETRIQ)  
25mg and 50mg extended-release tablets**

For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency, in patients who have an intolerance or inadequate response to an adequate trial of immediate-release oxybutynin.

Clinical Notes:

- Requests for the treatment of stress incontinence will not be considered.
- Not to be used in combination with other pharmacological treatments of OAB

Claim Note:

- If the patient has had a claim for oxybutynin in the previous 24 months, the adjudication system will recognize this information and the claim for mirabegron will be automatically reimbursed without the need for a written special authorization request.

**MODAFINIL (ALERTEC and generic brand)  
100mg tablet**

For the treatment of narcolepsy confirmed by a sleep study.

**MOMETASONE FUROATE/FORMOTEROL FUMARATE DIHYDRATE (ZENHALE)  
5mcg/50mcg, 5mcg/100mcg and 5mcg/200mcg per actuation metered-dose inhalers**

For patients with reversible obstructive airways disease who are:

- Stabilized on an inhaled corticosteroid and a long-acting beta2-adrenergic agonist  
OR
- Using optimal doses of inhaled corticosteroids but are still poorly controlled.

**MONTELUKAST (SINGULAIR and generic brands)**  
**4mg and 5mg chewable tablets**  
**10mg tablet**  
**4mg oral granules**

For the treatment of moderate to severe asthma in patients who:

- Are not adequately controlled with moderate to high dose inhaled corticosteroids despite compliance with treatment  
AND
- Require increasing amounts of short-acting beta2-adrenergic agonists.

**MOXIFLOXACIN (AVELOX)**  
**400mg tablet**

- For the completion of therapy instituted in the hospital setting for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB).
- For the treatment of severe pneumonia in nursing home patients.
- For the treatment<sup>1</sup> of CAP in patients;
  - with co-morbidity<sup>2</sup> upon radiographic confirmation of pneumonia,  
OR
  - who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate).
- For the treatment<sup>1</sup> of AECB in complicated patients<sup>3</sup> who have failed treatment with one of the following (amoxicillin, doxycycline, TMP-SMX, cefuroxime, macrolide, ketolide or amoxicillin-clavulanate).

Clinical Notes:

1. <sup>1</sup>If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.
2. <sup>2</sup>Co-morbidity includes chronic lung disease, malignancy, diabetes, liver, renal or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDs, smoking, malnutrition or acute weight loss.
3. <sup>3</sup>Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea  
AND
  - $FEV_1 < 50\%$  predicted  
OR
  - $FEV_1$  50-65% and one of the following:
    - $\geq 4$  exacerbations per year
    - Ischemic heart disease
    - Chronic oral steroid use
    - Antibiotic use in the past 3 months

Claim Notes:

- Prescriptions written by New Brunswick infectious disease specialists, medical microbiologists, medical oncologists, respirologists and internal medicine specialists will not require special authorization.

**NABILONE (CESAMET and generic brands)**  
**0.25mg, 0.5mg and 1mg capsules**

For the management of severe nausea and vomiting associated with cancer chemotherapy.

**NADROPARIN CALCIUM (FRAXIPARIN)**  
**Pre-filled syringes**  
**NADROPARIN CALCIUM (FRAXIPARIN FORTE)**  
**Pre-filled syringes**

See criteria under [Low Molecular Weight Heparins](#).

**NAFARELIN ACETATE (SYNAREL)**  
**2mg/mL nasal solution**

Approved for the hormonal management of endometriosis, including pain relief and reduction of endometriotic lesions.

Clinical Note:

- Requests will be considered for women age 18 and older.

Claim Note:

- Approval limits payment to a maximum of 6 months of therapy.

**NALTREXONE (REVIA)  
50mg tablet**

- For the treatment of alcohol dependence, as an adjunct to a comprehensive program to support abstinence, and reduce the risk of relapse.
- For the maintenance of opioid-free state in individuals who were previously opioid-dependent but have successfully completed detoxification. Treatment should not be attempted until the patient has remained opioid-free for 7 - 10 days. Requests will be considered only when used as an adjunct to psychosocial intervention. In the event that a patient participates in a program other than those offered by New Brunswick Addiction Services, details on the type of counselling/supportive program the patient will be involved in will be requested.

Continued coverage will require information on the outcome of therapy as well as patient's compliance with treatment programs.

Claim Note:

- Coverage will be approved initially for 12 weeks.

**NARATRIPTAN (AMERGE and generic brands)  
1mg and 2.5mg tablets**

- For the treatment of migraine<sup>1</sup> headache when:
  - Migraines are moderate<sup>2</sup> in severity and other therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective,  
OR
  - Migraine attacks are severe<sup>2</sup> or ultra severe<sup>2</sup>

Clinical Notes:

1. <sup>1</sup>As diagnosed based on current Canadian guidelines.
2. <sup>2</sup> Definitions:

- Moderate - pain is distracting causing need to slow down and limit activities;
- Severe - pain affects ability to concentrate and very difficult to continue with daily activities;
- Ultra severe - unable to speak or think clearly; not able to function; likely lying down or sleeping

Claim Notes:

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - patients with >3 migraines/month on average despite prophylactic therapy may be considered for up to a maximum of 12 doses / 30 days
- <sup>3</sup> Reimbursement will be available for a maximum quantity of triptan doses as outlined in criteria per 30 days regardless of the agent(s) used within the 30 day period.
- Special authorization for the products almotriptan 6.25mg and 12.5mg tablets, naratriptan 1mg and 2.5mg tablets, rizatriptan 5mg and 10mg tablets and wafers, sumatriptan 5mg and 20mg nasal spray and zolmitriptan 2.5mg tablets and orally dispersible tablets, 2.5mg and 5mg nasal spray will be considered as a set. Approvals will include all products in this list, however reimbursement will be available for a maximum quantity of one agent per month.

**NATALIZUMAB (TYSABRI)  
300mg/15mL vial**

Initial Request:

For the treatment of Relapsing-Remitting Multiple Sclerosis (RRMS) in patients who meet all the following criteria:

- The patient's physician is a neurologist experienced in the management of relapsing-remitting multiple sclerosis (RRMS);

AND

The patient;

- Has a current EDSS less than or equal to 5.0;

AND

- Has failed to respond to a full and adequate course (see note below) of at least ONE disease modifying therapy OR has contraindications/intolerance to at least TWO disease modifying therapies;

AND

- Has had ONE of the following types of relapses in the past year:

- The occurrence of one relapse with partial recovery during the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI;

OR

- The occurrence of two or more relapses with partial recovery during the past year;

OR

- The occurrence of two or more relapses with complete recovery during the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI.



Requirements for Initial Requests:

- The patient's physician provides documentation setting out the details of the patient's most recent neurological examination within ninety (90) days of the submitted request. This must include a description of any recent attacks, the dates, and the neurological findings.
- MRI reports do NOT need to be submitted with the initial request

Renewal Criteria:

- Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within that last 90 days)  
AND
- Patients must be stable or have experienced no more than 1 disabling attack/relapse in the past year;  
AND
- Recent Expanded Disability Status Scale (EDSS) score less than or equal to 5.0

Clinical Notes:

1. Failure to respond to a full and adequate course: defined as a trial of at least 6 months of interferon or glatiramer therapy AND experienced at least one disabling relapse (attack) while on interferon or glatiramer therapy.
2. Combination therapy of Natalizumab with other disease modifying therapies (e.g. Avonex, Betaseron, Copaxone, Rebif, Extavia, Gilenya) will not be funded.

Claim Note:

- Approval Period: 1 year

**NICOTINE (generic brands)  
2mg gum  
7mg, 14mg and 21mg patches**

For smoking cessation treatment in adults 18 years of age and older.

A maximum of 12 weeks of standard therapy will be reimbursed annually without special authorization for either nicotine replacement therapy (patches/gum) or a non-nicotine, prescription smoking cessation drug (Champix or Zyban).

Claim Notes:

- A maximum of 84 patches and 945 pieces of nicotine gum will be reimbursed annually without special authorization.
- Individuals who have a high probability of quitting with prolonged therapy may be approved under special authorization for up to an additional 28 patches. A maximum of three additional requests will be permitted annually (maximum of 84 patches).
- Individuals being treated within a program or clinic that participates in the Ottawa Model will qualify for additional reimbursement based on degree of dependence (e.g. number of cigarettes smoked prior to initiating cessation therapy). All special authorization requests for additional nicotine replacement therapy will require confirmation that the individual has agreed, or is already registered with, the Smokers Helpline (1-877-513-5333) or is participating in another form of smoking cessation counselling to be specified.
- Requests for special authorization should be submitted on the [Request for Additional Smoking Cessation Therapy Form](#).

**Important Links:**

- [Smokers Helpline Referral Form](#)
- [Smokers Helpline Online](#)
- [On the road to quitting](#)
- [Quit4life](#)

**NILOTINIB (TASIGNA)  
150mg capsule**

For the first-line treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.

**NILOTINIB (TASIGNA)  
200mg capsule**

For the treatment of chronic phase (CP) and accelerated phase (AP) Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in adult patients who:

- are resistant or intolerant to imatinib,  
OR
- intolerant to dasatinib

**NORETHINDRONE ACETATE / ESTRADIOL-17 $\beta$  (ESTALIS)  
140/50mcg and 250/50mcg transdermal patches**

For the treatment of menopausal symptoms in women for whom oral forms of HRT are not tolerated or indicated.

**OCRIPLASMIN (JETREA)  
2.5mg/mL intravitreal injection**

For the treatment of symptomatic vitreomacular adhesion (VMA) if the following clinical criteria and conditions are met:

- Diagnosis of VMA has been confirmed through optical coherence tomography.
- Patients do not have any of the following: large diameter macular holes (greater than 400 micrometres), high myopia (greater than 8 dioptre spherical correction or axial length greater than 28 millimetres), aphakia, history of retinal detachment, lens zonule instability, recent ocular surgery or intraocular injection (including laser therapy), proliferative diabetic retinopathy, ischemic retinopathies, retinal vein occlusions, exudative age-related macular degeneration, or vitreous hemorrhage.

Clinical Notes:

- Ocriplasmin should be administered by an ophthalmologist experienced in intravitreal injections.
- Treatment with ocriplasmin should be limited to a single injection per eye (i.e. retreatments are not covered).

**OFLOXACIN (OCUFLOX and generic brands)  
0.3% ophthalmic solution**

For the treatment of bacterial conjunctivitis.

Claim Note:

- Prescriptions written by New Brunswick ophthalmologists and optometrists do not require special authorization.

**OLANZAPINE (ZYPREXA and generic brands)  
2.5mg, 5mg, 7.5mg, 10mg and 15mg tablets  
OLANZAPINE (ZYPREXA ZYDIS and generic brands)  
5mg, 10mg, 15mg and 20mg oral disintegrating tablets**

- For the acute and maintenance treatment of schizophrenia and related psychotic disorders.
- For the acute treatment of manic or mixed episodes in bipolar I disorder in patients with intolerance or a history of failure to one other atypical antipsychotic.
- For maintenance treatment in patients with bipolar disorder who are currently stabilized on olanzapine.

Clinical Note:

- Advice from a psychiatrist is suggested prior to starting therapy.

Claim Note:

- Prescriptions written by New Brunswick psychiatrists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

**ONABOTULINUMTOXINA (BOTOX)  
50 Allergan units per vial (PIN 00903741) and 100 Allergan units per vial**

1. For the treatment of equinus foot deformity in cerebral palsy in patients 2 years of age and older.
2. To reduce the subjective symptoms and objective signs of cervical dystonia (spasmodic torticollis) in adults.
3. For the treatment of blepharospasm, hemifacial spasm (VII nerve disorder) and strabismus in patients 12 years of age and older.
4. For the treatment of upper and lower limb (at or below the knee) focal spasticity following stroke in adults. Initial approval period for focal spasticity following stroke will be 6 months. Continued approval will require documented benefit of improved passive and/or active range of motion, muscle tone, or improved gait (in the case of lower limb spasticity).

Clinical Note:

- The following conditions are excluded from coverage:
  - Chronic migraine
  - Chronic pain
  - Hyperhidrosis
  - Muscle contracture for support of perineal care.

**ONABOTULINUMTOXINA (BOTOX)  
200 Allergan units per vial (PIN 00999505)**

For the treatment of urinary incontinence due to neurogenic detrusor overactivity resulting from neurogenic bladder associated with multiple sclerosis (MS) or subcervical spinal cord injury (SCI) if the following conditions are met:

- patient failed to respond to behavioural modification and anticholinergics and/or is intolerant to anticholinergics
- subsequent treatments are provided at intervals no less than every 36 weeks

Clinical Note:

- Patients who fail to respond to initial treatment with onabotulinumtoxinA should not be retreated.

**ONDANSETRON (ZOFTRAN and generic brands)  
4mg and 8mg tablets  
4mg/5mL oral solution**

For the treatment of emesis in patients who are:

- receiving moderately or severely emetogenic chemotherapy  
OR
- receiving intravenous chemotherapy or radiotherapy and who have not experienced adequate control with other available antiemetics  
OR
- receiving any intravenous chemotherapy or radiotherapy and have experienced emesis with a prior cycle of chemotherapy with intolerable side effects to other antiemetics, including steroids and anti-dopaminergic agents.

Clinical Notes:

1. Only requests for the oral dosage forms are eligible for consideration. Usually a single oral dose pre-chemotherapy is sufficient to control symptoms.
2. Some patients may require additional therapy up to 48 hours after the last dose of chemotherapy or last radiation treatment. Benefit beyond 48 hours has not been established.
3. When used in combination with aprepitant, only a single oral dose pre-chemotherapy will be covered.

Claim Note:

- Prescription claims for up to a maximum of 12 tablets of ondansetron or 2 tablets of granisetron will be automatically reimbursed every 28 days when the prescription is written by an oncologist or an oncology clinical associate/general practitioners-oncology. If additional medication is required within a 28 day period subsequent to the initial prescription, a request should be made through special authorization.

**ONDANSETRON (ZOFTRAN ODT and generic brand)  
4mg and 8mg oral disintegrating tablets**

Requests will be considered for the treatment of emesis in patients who have difficulty swallowing oral tablets and are:

- receiving moderately or severely emetogenic chemotherapy  
OR
- receiving intravenous chemotherapy or radiotherapy and who have not experienced adequate control with other available antiemetics  
OR
- receiving any intravenous chemotherapy or radiotherapy and have experienced emesis with a prior cycle of chemotherapy with intolerable side effects to other antiemetics, including steroids and anti-dopaminergic agents.

Clinical Notes:

1. Only requests for the oral dosage forms are eligible for consideration. Usually a single oral dose pre-chemotherapy is sufficient to control symptoms.
2. Some patients may require additional therapy up to 48 hours after the last dose of chemotherapy or last radiation treatment. Benefit beyond 48 hours has not been established.
3. When used in combination with aprepitant, only a single oral dose prechemotherapy will be covered.

**OSELTAMIVIR (TAMIFLU)  
30mg, 45mg and 75mg capsules**

For beneficiaries residing in long-term care facilities\* during an influenza outbreak situation and further to the recommendation of a Medical Officer of Health:

- For treatment of long-term care residents with clinically suspected or lab confirmed influenza A or B. A clinically suspected case is one in which the patient meets the criteria of influenza-like illness and there is confirmation of influenza A or B circulating within the facility or surrounding community.

- For prophylaxis of long-term care residents where the facility has an influenza A or B outbreak. Prophylaxis should be continued until the outbreak is over. An outbreak is declared over 7 days after the onset of the last case in the facility.

**Clinical Note:**

- \*In these criteria, *long-term care facility* refers to a licensed nursing home and does not include special care homes.

**OSTEOPOROSIS DRUGS (etidronate and raloxifene)**

Requests for osteoporosis drugs for patients without documented fracture should reference the most recent (2010) version of the Canadian Association of Radiologist and Osteoporosis Canada (CAROC) table<sup>1</sup>, or the World Health Organization (WHO) Fracture Risk Assessment Tool (FRAX) <http://www.shef.ac.uk/FRAX/tool.jsp?lang=en> when determining whether the patient meets criteria for high (>20%) 10-year fracture risk.

**Fracture Risk Tables**

Women				Men			
Age (years)	10-YEAR RISK			Age (years)	10-YEAR RISK		
	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%		Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
	LOWEST T-SCORE femoral neck				LOWEST T-SCORE femoral neck		
50	> -2.5	-2.5 to -3.8	< -3.8	50	> -2.5	-2.5 to -3.9	< -3.9
55	> -2.5	-2.5 to -3.8	< -3.8	55	> -2.5	-2.5 to -3.9	< -3.9
60	> -2.3	-2.3 to -3.7	< -3.7	60	> -2.5	-2.5 to -3.7	< -3.7
65	> -1.9	-1.9 to -3.5	< -3.5	65	> -2.4	-2.4 to -3.7	< -3.7
70	> -1.7	-1.7 to -3.2	< -3.2	70	> -2.3	-2.3 to -3.7	< -3.7
75	> -1.2	-1.2 to -2.9	< -2.9	75	> -2.3	-2.3 to -3.8	< -3.8
80	> -0.5	-0.5 to -2.6	< -2.6	80	> -2.1	-2.1 to -3.8	< -3.8
85	> +0.1	+0.1 to -2.2	< -2.2	85	> -2.0	-2.0 to -3.8	< -3.8

<sup>1</sup>Ref: Can Assoc Radiol J, 2011; 62(4): 243-50

**ETIDRONATE (DIDRONEL and generic brands) 200mg tablets  
ETIDRONATE AND CALCIUM (generic brands) 400mg/500mg tablets**

For the treatment of osteoporosis:

- with documented fragility fracture when alendronate or risedronate are not tolerated or contraindicated;  
OR
- without documented fractures in patients at high 10-year fracture risk (see fracture risk tables) when alendronate or risedronate are not tolerated or contraindicated.

**RALOXIFENE (EVISTA and generic brands) 60mg tablets**

For the treatment of postmenopausal osteoporosis

- with documented fragility fracture when bisphosphonates are not tolerated or contraindicated;  
OR
- without documented fractures in patients at high 10-year fracture risk (see fracture risk tables) when bisphosphonates are not tolerated or contraindicated.

**OXCARBAZEPINE (TRILEPTAL and generic brand)  
150mg, 300mg and 600mg tablets  
60mg/mL suspension**

For the treatment of epilepsy in patients who have had an inadequate response or are intolerant to at least 3 other antiepileptics including carbamazepine.

**OXYBUTYNIN (DITROPAN XL)  
5mg and 10mg tablets**

For the treatment of overactive bladder with symptoms of urgency, urgency incontinence, and urinary frequency, in patients who have not tolerated a reasonable trial of immediate release oxybutynin.

Clinical Note:

- Requests for the treatment of stress incontinence will not be considered.

**OXYCODONE (OXY IR and generic and SUPEUDOL)  
5mg, 10mg and 20mg tablets (immediate release)**

For the treatment of moderate to severe cancer-related or chronic non-malignant pain.

**PALIPERIDONE (INVEGA SUSTENNA)  
50mg/0.5mL, 75mg/0.75mL, 100mg/mL and 150mg/1.5mL pre-filled syringes**

For the treatment of schizophrenia in patients:

- for whom compliance with an oral antipsychotic presents problems,  
OR
- who are currently receiving a typical depot antipsychotic and experiencing significant side effects (EPS or TD) or lack of efficacy.

**PANTOPRAZOLE SODIUM (PANTOLOC and generic brands)  
20mg and 40mg tablets**

See criteria under [Proton Pump Inhibitors](#).

**PAZOPANIB (VOTRIENT)  
200mg tablet**

1. As a first-line treatment for patients with advanced or metastatic clear cell renal carcinoma and good performance status.
2. For the treatment of advanced or metastatic renal cell (clear cell) carcinoma (mRCC) in patients who are unable to tolerate sunitinib and who have an ECOG performance status of 0 or 1.

Renewal Criteria:

- Written confirmation that the patient has benefited from therapy and is expected to continue to do so.

Claim Notes:

- Initial approval period: 1 year
- Renewal period: 1 year

**PEGFILGRASTIM (NEULASTA)  
6mg pre-filled syringe**

Requests will be considered for the following indications:

**Chemotherapy Support**

- Primary prophylaxis:
  - For use in previously untreated patients receiving a moderate to severely myelosuppressive chemotherapy regimen (i.e.  $\geq 40\%$  incidence of febrile neutropenia). Febrile neutropenia is defined as a temperature  $\geq 38.5^{\circ}\text{C}$  or  $> 38.0^{\circ}\text{C}$  three times in a 24 hour period and neutropenia with an absolute neutrophil count (ANC)  $< 0.5 \times 10^9/\text{L}$ .
- Secondary prophylaxis:
  - For use in patients receiving myelosuppressive chemotherapy who have experienced an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or
  - For use in patients who have experienced a dose reduction or treatment delay longer than one week, due to neutropenia.
- Dosing for chemotherapy support:
  - The recommended dosage of pegfilgrastim is a single subcutaneous injection of 6mg, administered once per cycle of chemotherapy. Pegfilgrastim should be administered no sooner than 24 hours after the administration of cytotoxic chemotherapy.

Clinical Notes:

1. Pegfilgrastim is not indicated and requests will not be considered for the following:
  - Myeloid malignancies
  - Pediatric patients with cancer receiving myelosuppressive chemotherapy
  - Non-malignant neutropenias
  - Stem-cell transplantation
  - Treatment of febrile neutropenia or in the prevention of febrile neutropenia in the palliative setting
2. Filgrastim (Neupogen<sup>®</sup>) dosing is 5 mcg/kg/day. For patients ≤ 60 kg who are prescribed filgrastim 300mcg for 9 or fewer days, the cost of filgrastim therapy is less than the cost of pegfilgrastim 6mg.

Claim Note:

- Requests will be considered when prescribed by, or on the advice of, a hematologist or medical oncologist.

**PEGINTERFERON ALFA-2A (PEGASYS)  
180mcg/0.5mL pre-filled syringe and ProClick Autoinjector**

Requests will be considered for the treatment of:

- Chronic hepatitis C (HCV RNA positive) for patients who cannot tolerate ribavirin.
  - Initial coverage of 24 weeks will be approved for all patients. Coverage for an additional 24 weeks will be approved for patients with HCV genotype 1.
  - A positive HCV RNA assay after 24 weeks of therapy is an indication to stop treatment.
- HBeAg negative chronic hepatitis B patients with compensated liver disease, liver inflammation and evidence of viral replication with demonstrated intolerance or failure to lamivudine therapy.
  - Maximum duration of coverage will be 48 weeks.

Claim Note:

- Requests will be considered from internal medicine specialists.

**PEGINTERFERON ALFA-2A AND RIBAVIRIN (PEGASYS RBV)  
180mcg injection and 200mg tablet (pre-filled syringe and ProClick Autoinjector)**

1. For the treatment of peginterferon and ribavirin treatment-naïve chronic hepatitis C (HCV RNA positive) patients.

Clinical Note:

- A positive HCV RNA assay after 24 weeks of therapy is an indication to stop treatment.

Claim Notes:

- Initial coverage of 24 weeks will be approved for all patients. Coverage for an additional 24 weeks will be approved for patients with HCV genotypes other than 2 and 3.
  - Requests will be considered from internal medicine specialists
2. For the treatment of patients with chronic hepatitis C genotype 1 infection (HCV RNA positive) in combination with boceprevir or telaprevir.

Claim Notes:

- Coverage will be approved for up to a total of 48 weeks in combination with boceprevir or telaprevir.
- Requests will be considered from internal medicine specialists

**PEGINTERFERON ALFA-2B AND RIBAVIRIN (PEGETRON and PEGETRON CLEARCLICK)  
50mcg injection and 200mg capsule, 80mcg injection and 200mg capsule  
100mcg injection and 200mg capsule, 120mcg injection and 200mg capsule  
150mcg injection and 200mg capsule**

1. For the treatment of peginterferon and ribavirin treatment-naïve chronic hepatitis C (HCV RNA positive) patients.

Clinical Note:

- A positive HCV RNA assay after 24 weeks of therapy is an indication to stop treatment.

Claim Notes:

- Initial coverage of 24 weeks will be approved for all patients. Coverage for an additional 24 weeks will be approved for patients with HCV genotypes other than 2 and 3.
  - Requests will be considered from internal medicine specialists
2. For the treatment of patients with chronic hepatitis C genotype 1 infection (HCV RNA positive) in combination with boceprevir or telaprevir.

Claim Notes:

- Coverage will be approved for up to a total of 48 weeks in combination with boceprevir or telaprevir.
- Requests will be considered from internal medicine specialists

**PERAMPANEL (FYCOMPA)  
2mg, 4mg, 6mg, 8mg, 10mg and 12mg tablets**

For the adjunctive treatment of refractory partial-onset seizures in patients who meet all of the following criteria:

- are under the care of a physician experienced in the treatment of epilepsy,  
AND
- are currently receiving two or more antiepileptic drugs,  
AND
- in whom less costly antiepileptic drugs\* are ineffective or not appropriate.

Clinical Notes:

1. The combination of lacosamide (Vimpat) and perampanel (Fycompa) will not be reimbursed.
2. \*Less costly antiepileptic drugs may include the following: carbamazepine, gabapentin, lamotrigine, phenytoin, topiramate, vigabatrin.

**PILOCARPINE (SALAGEN and generic brand)  
5mg tablet**

- For the treatment of the symptoms of xerostomia (dry mouth) due to salivary gland hypofunction caused by radiotherapy for cancer of the head and neck.
- For the treatment of the symptoms of xerostomia (dry mouth) and xerophthalmia (dry eyes) in patients with Sjögren's syndrome.

**PIOGLITAZONE (ACTOS and generic brands)  
15mg, 30mg and 45mg tablets**

For patients with type 2 diabetes who are not adequately controlled by diet, exercise and drug therapy. Drug therapy should include a trial of a sulfonylurea and metformin, alone and in combination, unless one of these agents is not tolerated or is contraindicated.

**PIRFENIDONE (ESBRIET)  
267mg capsule**

Initial approval criteria:

Adult patients who have a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF)\* confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.

\*Mild-moderate IPF is defined as: a FVC between 50-80% predicted, and a Percent Carbon Monoxide Diffusing Capacity (%DLCO) between 30-90% predicted.

Initial renewal criteria:

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of  $\geq 10\%$  from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Second renewal (12 months after initiation of therapy):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of  $\geq 10\%$  since initiation of therapy (baseline). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Claim Notes:

- Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)
- Renewal Approval period: 6 months
- Second renewal approval period: 12 months

**PLERIXAFOR (MOZOBIL)  
24mg/1.2mL solution for injection**

For use in combination with filgrastim to mobilize hematopoietic stem cells for subsequent autologous transplantation in patients with Non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM) if one of the following criteria are met:

- A PBCD34+ count of  $< 10$  cells/uL after 4 days of filgrastim;  
OR

- Less than 50% of the target CD34 yield is achieved on the 1st day of apheresis (after being mobilized with filgrastim alone or following chemotherapy);  
OR
- If a patient has failed a previous stem cell mobilization with filgrastim alone or following chemotherapy.

Claim Note:

- Reimbursement is limited to a maximum of 4 doses (0.24mg/kg given daily) for a single mobilization attempt and to prescriptions written by an oncologist or hematologist.

**POMALIDOMIDE (POMALYST)  
1mg, 2mg, 3mg and 4mg capsules**

For the treatment of patients with relapsed and/or refractory multiple myeloma who:

- Have previously failed at least two treatments including both bortezomib and lenalidomide, and
- Demonstrated disease progression on the last treatment.

Clinical Note:

- Requests for pomalidomide will be considered in rare instances where bortezomib is contraindicated or when patients are intolerant to it; however, in all cases patients should have failed lenalidomide which they may have received in the maintenance setting.

Claim Note:

- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**PRASUGREL HYDROCHLORIDE (EFFIENT)  
10mg tablet**

In combination with ASA for patients with:

- ST-elevated myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) who have not received antiplatelet therapy prior to arrival in the catheterization lab. Treatment must be initiated in hospital.  
OR
- Acute coronary syndrome who failed on optimal clopidogrel and ASA therapy as defined by definite stent thrombosis, or recurrent STEMI, or NSTEMI or UA after prior revascularization via PCI.

Clinical Notes:

1. Definite stent thrombosis, according to the Academic Research Consortium, is a total occlusion originating in or within 5 mm of the stent or is a visible thrombus within the stent or is within 5 mm of the stent in the presence of an acute ischemic clinical syndrome within 48 hours. Definite stent thrombosis must be confirmed by angiography or by pathologic evidence of acute thrombosis.
2. As per the product monograph, prasugrel is contraindicated in patients with a known history of transient ischemic attack or stroke; those with active pathological bleeding such as gastrointestinal bleeding or intracranial hemorrhage; and those with severe hepatic impairment (Child-Pugh Class C).
3. As per the product monograph, prasugrel is not recommended in patients  $\geq 75$  years of age because of the increase risk of fatal and intracranial bleeding; or those with body weight  $< 60$  kg because of increased risk of major bleeding due to an increase in exposure to the active metabolite of prasugrel.

Claim Notes:

- Approval will be for a maximum of 12 months.
- Prescriptions written by invasive (interventional) cardiologists do not require special authorization.

**PREGABALIN (LYRICA and generic brands)  
25mg, 50mg, 75mg, 150mg, 225mg and 300mg capsules**

For the treatment of neuropathic pain (e.g. diabetic peripheral neuropathy, postherpetic neuralgia) in patients who have failed a trial of a tricyclic antidepressant (e.g. amitriptyline, desipramine, imipramine, nortriptyline).



## PROTON PUMP INHIBITORS (Lansoprazole, Pantoprazole Sodium)

### Lansoprazole 15mg & 30mg capsules and Pantoprazole Sodium 20mg & 40mg tablets

Requests for lansoprazole and pantoprazole sodium will be considered for patients in whom there has been a therapeutic failure with regular benefit PPIs (e.g. rabeprazole, omeprazole).

#### Approval Periods

Requests for lansoprazole and pantoprazole sodium, meeting criteria above, will be considered for the following maximum approval periods:

Indication and Diagnostic Information	Maximum Approval Period
1 Symptomatic GERD or other reflux-associated indications (i.e. non-cardiac chest pain)	Considered for short-term (8-12 week) approval
2 Erosive/ulcerative esophagitis or Barrett's esophagus	Considered for long term approval
3 Zollinger-Ellison Syndrome	Considered for long-term approval
4 Gastric/duodenal ulcers in individuals who are <i>H. pylori</i> negative or having uninvestigated peptic ulcer disease (PUD)	Considered for up to 12 weeks
5 <i>H. pylori</i> positive patients with PUD	<i>H. pylori</i> regimens containing lansoprazole or pantoprazole sodium will be reimbursed only under special authorization.
6 Gastro-duodenal protection (ulcer prophylaxis) for high risk patients (e.g. high risk NSAID users)	Considered for one year with reassessment

### QUINAGOLIDE (NORPROLAC) 0.075mg, 0.15mg tablets

For the treatment of patients with hyperprolactinemia who have failed or are intolerant to bromocriptine.

### RALOXIFENE (EVISTA and generic brands) 60mg tablet

See criteria under [Osteoporosis Drugs](#).

### RANIBIZUMAB (LUCENTIS) 2.3 mg / 0.23 mL vial for intravitreal injection

#### 1. Neovascular (wet) age-related macular degeneration (AMD)

##### Initial Coverage:

For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) where all of the following apply to the eye to be treated:

- Best Corrected Visual Acuity (BCVA) is between 6/12 and 6/96
- The lesion size is less than or equal to 12 disc areas in greatest linear dimension
- There is evidence of recent (< 3 months) presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, or optical coherence tomography (OCT))
- Administration is to be done by a qualified ophthalmologist experienced in intravitreal injections.
- The interval between doses should not be shorter than 1 month.

##### Continued Coverage:

Treatment with ranibizumab should be continued only in people who maintain adequate response to therapy.

#### Clinical Notes:

1. Coverage will not be approved for patients:
  - With permanent retinal damage as defined by the Royal College of Ophthalmology guidelines
  - Receiving concurrent treatment with verteporfin.
2. Ranibizumab should be permanently discontinued if any one of the following occurs:
  - Reduction in BCVA in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology
  - Reductions in BCVA of 30 letters or more compared to either baseline and/or best recorded level since baseline as this may indicate either poor treatment effect, adverse events or both.
  - There is evidence of deterioration of the lesion morphology despite optimum treatment over 3 consecutive visits.

#### Claim Notes:

- An initial claim of up to two vials of ranibizumab (one vial per eye treated) will be automatically reimbursed when prescribed by an ophthalmologist. If additional medication is required, a request should be made through special authorization.
- The NBPDP will limit reimbursement to a maximum of 1 vial of ranibizumab per eye treated every 30 days. Claims submitted for greater than 1 vial, or submitted within 30 days of a previous claim will not be reimbursed.
- Please refer to [quantities for claims submissions](#) for the correct unit of measure.

## 2. Diabetic macular edema (DME)

#### **Initial coverage:**

For the treatment of visual impairment due to diabetic macular edema (DME) in patients who meet all of the following criteria:

- clinically significant centre-involving macular edema for whom laser photocoagulation is also indicated
- hemoglobin A1c test in the past 6 months with a value of less than or equal to 11%
- best corrected visual acuity of 20/32 to 20/400
- central retinal thickness greater than or equal to 250 micrometers

#### **Renewal Criteria:**

- confirm that a hemoglobin A1c test in the past 6 months had a value of less than or equal to 11%
- date of last visit and results of best corrected visual acuity at that visit
- date of last OCT and central retinal thickness on that examination
- if ranibizumab is being administered monthly, please provide details on the rationale

#### Clinical Note:

- Treatment should be given monthly until maximum visual acuity is achieved (i.e. stable visual acuity for three consecutive months while on ranibizumab). Thereafter, the patient's visual acuity should be monitored monthly. Treatment should be resumed when monitoring indicates a loss of visual acuity due to DME until stable visual acuity is reached again for three consecutive months.

#### Claim Notes:

- Approval Period: 1 year
- Claims submitted by pharmacies for reimbursement of Lucentis should be billed **per vial**.
- Lucentis is supplied by the manufacturer as a 2.3 mg/0.23 mL vial, however CPhA3 messaging for the online submission of pharmacy claims permits transmission of quantities to only one decimal place. Since the 0.23 mL vial cannot be adjudicated to two decimal places, this product should be claimed per vial.
- Please refer to [quantities for claims submissions](#) for the correct unit of measure.

## REGORAFENIB (STIVARGA) 150mg tablet

For the treatment of patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) who have had disease progression on, or intolerance to, imatinib and sunitinib, and who have an ECOG performance status of 0 or 1.

#### Renewal Criteria:

- Written confirmation that the patient continues to benefit from therapy.

#### Clinical Note:

- Recommended dose: 160mg once daily (3 weeks on, 1 week off).

#### Claim Notes:

- Initial approval duration: 6 months
- Renewal approval duration: 6 months

**REPAGLINIDE (GLUCONORM and generic brands)  
0.5mg, 1mg and 2mg tablets**

For patients with type 2 diabetes who are not adequately controlled by diet and exercise and glyburide and/or metformin or who have frequent or severe hypoglycemic episodes despite dosage adjustment of glyburide.

**RIBAVIRIN (IBAVYR)  
400mg and 600mg tablets**

For use in combination with other drugs for the treatment of chronic hepatitis C. The applicable criteria for the combination regimen must be met.

**RIFABUTIN (MYCOBUTIN)  
150mg tablet**

Requests will be considered for the prophylaxis of disseminated Mycobacterium avium complex (MAC) disease in the following patients:

- HIV infected patients with an AIDS defining diagnosis and CD4+ cell count less than or equal to 200/mm<sup>3</sup>.
- HIV positive patients without an AIDS defining diagnosis and CD4+ cell count less than or equal to 100/mm<sup>3</sup>.

**RILUZOLE (RILUTEK and generic brands)  
50mg tablet**

For the treatment of amyotrophic lateral sclerosis (ALS) or Lou Gehrig's Disease, when initiated by a physician with expertise in the management of ALS in patients who have:

- A probable or definite diagnosis of ALS as defined by the World Federation of Neurology criteria.
- ALS symptoms for less than five years.
- FVC > 60 % predicted upon initiation of therapy.
- No tracheostomy for invasive ventilation

Clinical Note:

- Coverage cannot be renewed once the patient has a tracheostomy for the purpose of invasive ventilation.

Claim Note:

- Requests will be approved for a maximum of six months coverage.

**RIOCIGUAT (ADEMPAS)  
0.5mg, 1mg, 1.5mg, 2mg, and 2.5mg film-coated tablets**

For the treatment of inoperable chronic thromboembolic pulmonary hypertension (CTEPH) World Health Organization [WHO] Group 4) or persistent or recurrent CTEPH after surgical treatment in adult patients (18 years of age or older) with WHO Functional Class II or III pulmonary hypertension.

Clinical Note:

- Requests will be considered from physicians with experience in the diagnosis and treatment of CTEPH.

Claim Note:

- Approval duration: 1 year

**RISEDRONATE (ACTONEL and generic brand)  
30mg tablet**

For the treatment of Paget's disease.

**RISPERIDONE (RISPERDAL M and generic brands)  
0.5mg, 1mg, 2mg, 3mg and 4mg oral disintegrating tablets**

1. For the treatment of schizophrenia and related psychotic disorders.
2. For use in severe dementia for the short-term symptomatic management of inappropriate behaviour due to aggression and/or psychosis.
3. For the acute management of manic episodes associated with Bipolar 1 disorder.

Clinical Note:

- Requests will be considered for patients who have difficulty swallowing oral tablets.

Claim Note:

- Prescriptions written by New Brunswick psychiatrists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

## **RISPERIDONE (RISPERDAL CONSTA)**

### **Prolonged release suspension for injection 12.5mg, 25mg, 37.5mg and 50mg vials**

For the treatment of schizophrenia in patients:

- for whom compliance with an oral antipsychotic presents problems,  
OR
- who are currently receiving a typical depot antipsychotic and experiencing significant side effects (EPS or TD) or lack of efficacy

## **RITUXIMAB (RITUXAN)**

### **10mg/mL injection**

#### **1. Rheumatoid Arthritis**

- For the treatment of adult patients with severe active rheumatoid arthritis who have failed to respond to an adequate trial with an anti-TNF agent.

#### Clinical Notes:

- Rituximab will not be reimbursed concomitantly with anti-TNF agents.
- Approval for re-treatment with rituximab will only be considered for patients who have achieved a response, followed by a subsequent loss of effect and, after an interval of no less than six months from the previous dose.

#### **2. Polyangiitis**

- For the induction of remission in patients with severely active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have severe intolerance or other contraindication to cyclophosphamide, or who have failed an adequate trial of cyclophosphamide.

## **RIVAROXABAN (XARELTO)**

### **10mg film-coated tablet**

#### **Venous thromboembolism prophylaxis (following total knee or total hip replacement surgery)**

- For the prophylaxis of venous thromboembolism as an alternative to low molecular weight heparins for total knee replacement (usual duration up to 14 days) OR total hip replacement surgery (usual duration up to 35 days).

#### Claim Notes:

- The maximum dose of rivaroxaban that will be reimbursed is 10 mg daily for up to 30 days during a 6 month period.
- Subsequent requirements for prophylaxis within a 6 month period (i.e. second joint replacement procedure within the 6 month period) will require Special Authorization.

## **RIVAROXABAN (XARELTO)**

### **15mg and 20mg film-coated tablets**

#### **Atrial fibrillation**

For the prevention of stroke and systemic embolism in at-risk patients with non-valvular atrial fibrillation for whom:

- Anticoagulation is inadequate following a at least a two month trial on warfarin; or
- Warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

#### Clinical Notes:

1. The following patient groups are excluded from coverage for rivaroxaban for atrial fibrillation:
  - Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min)
  - Patients 75 years of age or older without documented stable renal function
  - Patients with hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis
  - Patients with prosthetic heart valves.
2. At-risk patients with atrial fibrillation are defined as those with a CHADS<sub>2</sub> score of ≥ 1. Although the ROCKET-AF trial included patients with higher CHADS<sub>2</sub> scores (≥ 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS<sub>2</sub> score of 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a CHADS<sub>2</sub> score of 1.
3. Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e., adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
4. Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see rivaroxaban product monograph).
5. Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months (i.e. 30-49 mL/min for 15 mg once daily dosing or ≥ 50 mL/min for 20 mg once daily dosing).

6. There is currently no data to support that rivaroxaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, rivaroxaban is not recommended in these populations.
7. Patients starting rivaroxaban should have ready access to appropriate medical services to manage a major bleeding event.

#### **Venous thromboembolic events (VTE) treatment**

For the treatment of VTE (deep vein thrombosis (DVT) or pulmonary embolism (PE)).

##### Clinical Notes:

- The recommended dose of rivaroxaban for patients initiating DVT or PE treatment is 15mg twice daily for 3 weeks, followed by 20mg once daily.
- Drug plan coverage for rivaroxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.
- Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

##### Claim Note:

- Approval Period: Up to 6 months

#### **RIVASTIGMINE (EXELON and generic brands) 1.5mg, 3mg, 4.5mg and 6mg capsules 2mg/mL oral liquid**

See criteria under [Cholinesterase Inhibitors](#).

#### **RIZATRIPTAN (MAXALT and generic brands) 5mg and 10mg tablets RIZATRIPTAN (MAXALT RPD and generic brands) 5mg and 10mg oral disintegrating tablets**

- For the treatment of migraine<sup>1</sup> headache when:
  - Migraines are moderate<sup>2</sup> in severity and other therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective,
  - OR
  - Migraine attacks are severe<sup>2</sup> or ultra severe<sup>2</sup>

##### Clinical Notes:

- <sup>1</sup>As diagnosed based on current Canadian guidelines.
- <sup>2</sup> Definitions:
  - Moderate - pain is distracting causing need to slow down and limit activities;
  - Severe - pain affects ability to concentrate and very difficult to continue with daily activities;
  - Ultra severe - unable to speak or think clearly; not able to function; likely lying down or sleeping

##### Claim Notes:

- A maximum of 72 tablets will be reimbursed annually without special authorization. If additional medication is required within the year, a request should be made through special authorization.
- Patients with >3 migraines/month on average despite prophylactic therapy may be considered for up to a maximum of 12 doses / 30 days.

#### **RUFINAMIDE (BANZEL) 100mg, 200mg and 400mg tablets**

For the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome for patients who meet all of the following criteria:

- are under the care of a physician experienced in treating Lennox-Gastaut syndrome-associated seizures,
- AND
- are currently receiving two or more antiepileptic drugs,
- AND
- in whom less costly antiepileptic drugs are ineffective or not appropriate.

#### **RUXOLITINIB (JAKAVI) 5mg, 15mg, 20mg tablets**

For patients with intermediate to high risk symptomatic Myelofibrosis (MF) as assessed using the Dynamic International Prognostic Scoring System (DIPSS) Plus or patients with symptomatic splenomegaly. Patients should have ECOG performance status ≤3 and be either previously untreated or refractory to other treatment.

**SALMETEROL/FLUTICASONE (ADVAIR)  
50/100mcg, 50/250mcg and 50/500mcg discus  
25/125mcg and 25/250mcg metered dose inhalers**

**Reversible Obstructive Airway Disease**

- For patients with reversible obstructive airways disease who are:
  - Stabilized on an inhaled corticosteroid and a long-acting beta2-adrenergic agonist,  
OR
  - Using optimal doses of inhaled corticosteroids but are still poorly controlled.

**Chronic Obstructive Pulmonary Disease**

- For the treatment of chronic obstructive pulmonary disease (COPD) if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).
- Coverage can be provided without a trial of short-acting agent if there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1 /FVC ratio < 0.7) and significant symptoms (i.e. Medical Research Council (MRC) Dyspnea Scale score of 3-5).
- Combination therapy with a long-acting muscarinic antagonist (LAMA) AND a long-acting beta2-adrenergic agonist/inhaled corticosteroid (LABA/ICS) will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms i.e. MRC score of 3-5)  
AND
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids.

Clinical Note:

- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale). Spirometry reports from any point in time will be accepted.

Medical Research Council (MRC) Dyspnea Scale

COPD Stage	Symptoms
MODERATE – MRC 3 to 4	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
SEVERE – MRC 5	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

**SALMETEROL XINAFOATE (SEREVENT)  
50mcg diskus**

**Reversible Obstructive Airway Disease:**

- For the treatment of patients, 12 years of age or older, with reversible obstructive airway disease who are using optimal corticosteroid treatment, but are still poorly controlled.

**Chronic Obstructive Pulmonary Disease**

- For the treatment of chronic obstructive pulmonary disease (COPD) if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).
- Coverage can be provided without a trial of short-acting agent if there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1 /FVC ratio < 0.7) and significant symptoms (i.e. Medical Research Council (MRC) Dyspnea Scale score of 3-5).
- Combination therapy with tiotropium AND a long-acting beta2-adrenergic agonist/inhaled corticosteroid (LABA/ICS) will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms i.e. MRC score of 3-5)  
AND
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids.

Clinical Note:

- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale). Spirometry reports from any point in time will be accepted.

Medical Research Council (MRC) Dyspnea Scale

COPD Stage	Symptoms
MODERATE – MRC 3 to 4	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
SEVERE – MRC 5	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

Claim Note:

- Prescriptions written by certified New Brunswick respirologists do not require special authorization. Subsequent refills ordered by other practitioners will not require special authorization.

**SAXAGLIPTIN (ONGLYZA)  
2.5mg and 5mg tablets**

For the treatment of type 2 diabetes mellitus, in addition to metformin and a sulfonylurea, in patients with inadequate glycemic control on metformin and a sulfonylurea and for whom insulin is not an option.

**SEVELAMER (RENAGEL)  
800mg tablet**

Treatment of severe renal failure, where a calcium salt is contraindicated or not tolerated or when a phosphate binder is needed in association with a calcium salt, where a calcium salt alone does not produce optimal control of the hyperphosphatemia.

Claim Note:

- The prescription must be initiated by a nephrologist.

**SILDENAFIL CITRATE (REVATIO and generic brands)  
20mg tablet**

- For the treatment of patients with World Health Organization (WHO) functional class III idiopathic pulmonary arterial hypertension (IPAH) who do not demonstrate vasoreactivity on testing or who do demonstrate vasoreactivity on testing but fail a trial of calcium channel blockers.
- For the treatment of patients with World Health Organization (WHO) functional class III pulmonary arterial hypertension (PAH) associated with connective tissue diseases who do not respond to conventional therapy.
- Diagnosis of PAH should be confirmed by cardiac catheterization.

Claim Note:

- The maximum dose of sildenafil that will be reimbursed is 20mg three times daily.

**SIMEPREVIR (GALEXOS)  
150mg capsules**

For the treatment of chronic hepatitis C genotype 1 infection in patients with compensated liver disease, in combination with peginterferon alpha and ribavirin, if the following criteria are met:

- Detectable levels of hepatitis C virus (HCV) RNA in the last six months.
- Fibrosis stage of F2, F3 or F4 (Metavir score or equivalent).

Exclusion Criteria:

- Patients with the NS3 Q80K polymorphism should not be treated with simeprevir.
- Patients who have received a prior full therapeutic course of boceprevir or telaprevir in combination with peginterferon alpha and ribavirin and did not receive an adequate response.
- Decompensated liver disease.
- Patients less than 18 years old.
- Patients who have had prior organ transplant including liver transplant.
- Simeprevir in combination with sofosbuvir.

Clinical Notes:

1. Recommended dose is 150mg once daily in combination with peginterferon alpha and ribavirin.

2. Duration of treatment is to be determined using Response-Guided Therapy.

Patient Group	HCV RNA at Week 4	Triple Therapy Simeprevir, Peginterferon alfa and Ribavirin	Dual Therapy Peginterferon alfa and Ribavirin	Total Treatment Duration
Treatment-Naïve and Prior Relapsers	Undetectable	First 12 weeks	Additional 12 weeks	24 weeks
	<25 IU/mL detectable	First 12 weeks	Additional 36 weeks	48 weeks
Prior Non- Responders (Including Partial and Null Responder)	Undetectable or <25 IU/mL detectable	First 12 weeks	Additional 36 weeks	48 weeks

3. Discontinuation of treatment is recommended in patients with inadequate on-treatment virologic response since it is unlikely that they will achieve a sustained virologic response and may develop treatment-emergent resistance.

HCV RNA	Action
Treatment Week 4: $\geq 25$ IU/mL	Discontinue simeprevir, peginterferon alfa and ribavirin
Treatment Week 12: detectable	Discontinue peginterferon alfa and ribavirin (treatment with simeprevir is complete at Week 12)
Treatment Week 24: detectable	Discontinue peginterferon alfa and ribavirin

Please refer to the product monograph for full prescribing information.

Claim Notes:

- Only one course of treatment (for up to 12 weeks duration) will be approved.
- Renewals will not be considered.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**SITAGLIPTIN (JANUVIA)**  
**25mg, 50mg and 100mg tablets**  
**SITAGLIPTIN / METFORMIN (JANUMET)**  
**50mg/500mg, 50mg/850mg and 50mg/1000mg tablets**  
**METFORMIN / SITAGLIPTIN (JANUMET XR)**  
**1000mg/50mg extended release tablet**

For the treatment of Type 2 diabetes mellitus in patients for whom NPH insulin is not an option and:

- Who have inadequate glycemic control while on optimal doses of metformin and a sulfonylurea when added as a third agent;  
OR
- In combination with metformin when a sulfonylurea is not suitable due to contraindications or intolerance;  
OR
- As monotherapy when metformin and sulfonylurea are not suitable due to contraindications or intolerance

**SODIUM FERRIC GLUCONATE COMPLEX (FERRLECIT)**  
**12.5mg/mL injection**

For the treatment of iron deficiency anemia in patients who

- are intolerant to oral iron replacement products,  
OR
- have not responded to adequate therapy with oral iron.



**SOFOSBUVIR (SOVALDI)  
400mg tablet**

For the treatment of adult patients 18 years of age or older with chronic hepatitis C infection with compensated liver disease (including compensated cirrhosis) as follows:

<b>Approval Period and Regimen</b>	
<b>Genotype 1:</b> <ul style="list-style-type: none"> <li>Treatment-naïve patients</li> </ul>	12 weeks of sofosbuvir in combination with PegIFN/RBV
<b>Genotype 2:</b> <ul style="list-style-type: none"> <li>Treatment-naïve patients in whom interferon (IFN) is medically contraindicated, or</li> <li>Peginterferon / ribavirin (PegIFN/RBV) treatment-experienced patients</li> </ul>	12 weeks of sofosbuvir in combination with RBV
<b>Genotype 3:</b> <ul style="list-style-type: none"> <li>Treatment-naïve patients in whom IFN is medically contraindicated, or</li> <li>PegIFN/RBV treatment-experienced patients</li> </ul>	24 weeks of sofosbuvir in combination with RBV

Patients must also meet ALL of the following:

- Prescribed by a hepatologist, gastroenterologist, or an infectious disease specialist (or other physician experienced in treating hepatitis C).
- Lab-confirmed hepatitis C genotype 1, 2 or 3.
- Patient has a quantitative HCV RNA value within the last 6 months.
- Fibrosis stage F2 or greater (Metavir scale or equivalent).

Exclusion Criteria:

- Patients currently being treated with another HCV antiviral agent.
- Patients who have previously received a treatment course of sofosbuvir (re-treatment requests will not be considered).

Clinical Notes:

- Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (5-6).
- Medical contraindication to interferon is defined as hypersensitivity to peginterferon or interferon alfa-2a or 2b, polyethylene glycol or any component of the formulation resulting in discontinuation of therapy; or presence of significant clinical comorbidities which are deemed to have a high risk of worsening with interferon treatment. Details are required regarding a patient's contraindications and/or risk of worsening significant comorbidities.
- Genotype 2 or 3 treatment-experienced patients are patients who have previously been treated with PegIFN/RBV and did not receive adequate response.
- HIV / HCV co-infected patients may be considered as per criteria listed above.

Claim Note:

- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

**SOFOSBUVIR / LEDIPASVIR (HARVONI)  
400mg / 90mg tablet**

For the treatment of chronic hepatitis C genotype 1 infection in adult patients.

<b>Genotype 1</b>	<b>Approval Period</b>
Treatment naïve patients with no cirrhosis, viral load < 6 million IU/mL	8 weeks
Treatment naïve patients with no cirrhosis, viral load ≥ 6 million IU/mL or Treatment naïve patients with compensated cirrhosis or Treatment-experienced patients with no cirrhosis	12 weeks
Treatment-experienced patients with compensated cirrhosis	24 weeks

Patients must also meet all of the following criteria:

1. Prescribed by a hepatologist, gastroenterologist or an infectious disease specialist (or other physician experienced in treating hepatitis C)
2. Lab-confirmed hepatitis C genotype 1
3. Patient has a quantitative HCV RNA value within the last 6 months
4. Fibrosis stage F2 or greater (Metavir scale or equivalent)

Exclusion Criteria:

- Patients currently being treated with another HCV antiviral agent.
- Patients who have previously received a treatment course of ledipasvir/sofosbuvir (re-treatment requests will not be considered).

Clinical notes:

1. For treatment naïve patients with no cirrhosis, viral load < 6 million IU/mL, evidence has shown that the SVR rates with the 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized as a Health Canada approved treatment option. Patients with severe fibrosis/borderline cirrhosis (F3-4) or HIV/HCV co-infected patients may be considered for 12 weeks coverage.
2. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (5-6)
3. Treatment-experienced patients are patients who have previously been treated with peginterferon / ribavirin (PegIFN/RBV) regimen, including regimens containing HCV protease inhibitors and did not receive adequate response.
4. HIV-HCV co-infected patients may be considered as per criteria listed above.

Claim Note:

- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions as outlined [here](#).

### **SOLIFENACIN (VESICARE and generic brands) 5mg and 10mg tablets**

For the treatment of overactive bladder with symptoms of urgency, urgency incontinence, and urinary frequency, in patients who have not tolerated a reasonable trial of immediate release oxybutynin.

Clinical Note:

- Requests for the treatment of stress incontinence will not be considered.

Claim Note:

- If the patient has had a claim for oxybutynin in the previous 24 months, the adjudication system will recognize this information and the claim for solifenacin will be automatically reimbursed without the need for a written special authorization request.

### **SOMATROPIN (GENOTROPIN)**

**0.6mg, 0.8mg, 1mg, 1.2mg, 1.4mg, 1.6mg, 1.8mg, 2mg MiniQuick® pre-filled syringes  
5.3mg, 12mg GoQuick® pre-filled pens**

#### **1. Growth Hormone Deficiency in Children**

For the treatment of growth hormone deficiency in children under the age of 18.

Claim Notes:

- Must be prescribed by, or in consultation with, an endocrinologist.
- Somatropin is a regular benefit for Plan T

#### **2. Turner Syndrome**

For the treatment of short stature associated with Turner Syndrome in patients whose epiphyses are not closed.

Claim Note:

- Must be prescribed by, or in consultation with, an endocrinologist.

### **SOMATROPIN (HUMATROPE)**

**1mg, 6mg, 12mg and 24mg/vial injection**

#### **1. Growth Hormone Deficiency in Children**

For the treatment of growth hormone deficiency in children under the age of 18.

Claim Notes:

- Must be prescribed by, or in consultation with, an endocrinologist.
- Somatropin is a regular benefit for Plan T.

## 2. Turner Syndrome

For the treatment of short stature associated with Turner Syndrome in patients whose epiphyses are not closed.

### Claim Note:

- Must be prescribed by, or in consultation with, an endocrinologist.

### **SOMATROPIN (NUTROPIN AQ Pen Cartridge)**

10mg/2mL pen cartridge

### **SOMATROPIN (NUTROPIN AQ NuSpin)**

5mg/2mL, 10mg/2mL, and 20mg/2mL cartridges

### **SOMATROPIN (SAIZEN)**

3.33mg, 5mg and 8.8mg/vial injections

6mg, 12mg and 20mg cartridges

## 1. Growth Hormone Deficiency in Children

For the treatment of growth hormone deficiency in children under the age of 18.

### Claim Notes:

- Must be prescribed by, or in consultation with, an endocrinologist.
- Somatropin is a regular benefit for Plan T.

## 2. Turner Syndrome

For the treatment of short stature associated with Turner Syndrome in patients whose epiphyses are not closed.

### Claim Note:

- Must be prescribed by, or in consultation with, an endocrinologist.

## 3. Chronic Renal Insufficiency

For the treatment of children with growth failure associated with chronic renal insufficiency, up to the time of renal transplantation, who meet the following criteria:

- A glomerular filtration rate less than or equal to 1.25 mL/s/1.73m<sup>2</sup> (75 mL/min/1.73m<sup>2</sup>)
  - Evidence of growth impairment:
    - Z score (HSDS) less than -1.88 (HSDS = height standard deviation score, a statistical comparison to the average of normal values for age and sex) or height-for-age at the 3rd percentile
- OR
- Height velocity-for-age SDS less than -1.88 or height velocity-for-age less than 3<sup>rd</sup> percentile, persisting for greater than 3 months despite treatment of nutritional deficiencies and metabolic abnormalities.

### Claim Note:

- Somatropin must be prescribed by, or in consultation with, a specialist in pediatric nephrology.

### **SOMATROPIN (OMNITROPE)**

3.33mg and 6.7mg/cartridges

For the treatment of growth hormone deficiency in children under the age of 18.

### Claim Notes:

- Must be prescribed by, or in consultation with, an endocrinologist.
- Somatropin is a regular benefit for Plan T.

### **SORAFENIB (NEXAVAR)**

200mg tablet

#### **Metastatic Renal Cell Carcinoma (MRCC)**

As second-line therapy for patients with histologically confirmed metastatic clear cell renal cell carcinoma, who:

- have disease progression after prior cytokine therapy (e.g. interferon; aldesleukin) within the previous 8 months;
- AND
- have a performance status of 0 or 1 on the basis of the Eastern Cooperative Oncology Group (ECOG) criteria<sup>†</sup>;
- AND
- have a favourable or intermediate risk status, according to the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic score.

Renewal criteria:

- Written confirmation that the patient has benefited from therapy and is expected to continue to do so.

### Clinical Note:

- <sup>†</sup> Patients who are asymptomatic and those who are symptomatic but completely ambulant.

### Claim Notes:

- Initial approval period: 1 year.
- Renewal period: 1 year.

### **Advanced Hepatocellular Carcinoma (HCC)**

For patients with Child-Pugh Class A\* who have:

- A performance status of 0,1, or 2<sup>†</sup> on the basis of the Eastern Cooperative Oncology Group (ECOG) criteria;  
**AND**
- Either progressed on trans-arterial chemoembolization (TACE) or not suitable for the TACE procedure.
- Coverage may be renewed for patients with documentation of radiography and/or scan results indicating no progression

#### Clinical Notes:

1. Sorafenib will not be reimbursed if used with induction or adjuvant intent along with other curative-intent treatments; for maintenance therapy after trans-arterial chemoembolization; or if patients have Child-Pugh B or Child-Pugh C cirrhosis.
2. \*A Child-Pugh score of 5-6 is considered class A (well-compensated disease); 7-9 is class B (significant functional compromise); and 10-15 is class C (decompensated disease).
3. <sup>†</sup> Patients who are asymptomatic and those who are symptomatic and in bed less than 50% of the time.
4. The Memorial Sloan-Kettering Cancer Center (MSKCC) Prognostic Score categorizes patients into three risk groups according to the number of pre-treatment risk factors present: Favourable = none; Intermediate = one or two; Poor = three or more. Pre-treatment risk factors:
  - Low Karnofsky performance status (<80%)
  - Lactate Dehydrogenase level greater than 1.5 times the upper limit of normal
  - Hemoglobin level below the lower limit of normal
  - High corrected serum calcium level (>10 mg/dL or 2.5 mmol/L)
  - Interval of less than 1 year between diagnosis and treatment

#### Claim Notes:

- Initial approval period: 6 months
- Approval period for renewal: 1 year

### **STIRIPENTOL (DIACOMIT)**

**250mg and 500mg capsules**

**250mg and 500mg powder for suspension**

For use in combination with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (Dravet syndrome), whose seizures are not adequately controlled with clobazam and valproate alone.

#### Clinical Note:

- The patient must be under the care of a neurologist or a pediatrician.

### **SUMATRIPTAN (IMITREX AND IMITREX DF and generic brands)**

**50mg and 100mg tablets**

- For the treatment of migraine<sup>1</sup> headache when:
  - Migraines are moderate<sup>2</sup> in severity and other therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective,  
**OR**
  - Migraine attacks are severe<sup>2</sup> or ultra severe<sup>2</sup>

#### Clinical Notes:

1. <sup>1</sup>As diagnosed based on current Canadian guidelines.
2. <sup>2</sup>Definitions:
  - Moderate - pain is distracting causing need to slow down and limit activities;
  - Severe - pain affects ability to concentrate and very difficult to continue with daily activities;
  - Ultra severe - unable to speak or think clearly; not able to function; likely lying down or sleeping

#### Claim Notes:

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - patients with >3 migraines/month on average despite prophylactic therapy may be considered for up to a maximum of 12 doses / 30 days
- <sup>3</sup> Reimbursement will be available for a maximum quantity of triptan doses as outlined in criteria per 30 days regardless of the agent(s) used within the 30 day period.
- Special authorization for the products almotriptan 6.25mg and 12.5mg tablets, naratriptan 1mg and 2.5mg tablets, rizatriptan 5mg and 10mg tablets and wafers, sumatriptan 5mg and 20mg nasal spray and zolmitriptan 2.5mg tablets and orally dispersible tablets, 2.5mg and 5mg nasal spray will be considered as a set. Approvals will include all products in this list, however reimbursement will be available for a maximum quantity of one agent per month.

### **SUMATRIPTAN (IMITREX NASAL SPRAY) 5mg and 20mg nasal sprays**

- For the treatment of migraine<sup>1</sup> headache of moderate<sup>2</sup> intensity when other therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective AND patients have not responded to oral sumatriptan, zolmitriptan, rizatriptan and naratriptan.
- For the treatment of migraine<sup>1</sup> headache of severe<sup>2</sup> or ultra severe<sup>2</sup> intensity when patients have not responded to oral sumatriptan, zolmitriptan, rizatriptan and/or naratriptan.

#### Clinical Notes:

1. <sup>1</sup>As diagnosed based on current Canadian guidelines.
2. <sup>2</sup>Definitions:
  - Moderate - pain is distracting causing need to slow down and limit activities;
  - Severe - pain affects ability to concentrate and very difficult to continue with daily activities;
  - Ultra severe - unable to speak or think clearly; not able to function; likely lying down or sleeping

#### Claim Notes:

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - patients with >3 migraines/month on average despite prophylactic therapy may be considered for up to a maximum of 12 doses / 30 days
- <sup>3</sup>Reimbursement will be available for a maximum quantity of triptan doses as outlined in criteria per 30 days regardless of the agent(s) used within the 30 day period.
- Special authorization for the products almotriptan 6.25mg and 12.5mg tablets, naratriptan 1mg and 2.5mg tablets, rizatriptan 5mg and 10mg tablets and wafers, sumatriptan 5mg and 20mg nasal spray and zolmitriptan 2.5mg tablets and orally dispersible tablets, 2.5mg and 5mg nasal spray will be considered as a set. Approvals will include all products in this list, however reimbursement will be available for a maximum quantity of one agent per month.

### **SUMATRIPTAN (IMITREX INJECTION and generic brand) 6mg injection**

- For the treatment of migraine<sup>1</sup> headache of moderate<sup>2</sup> intensity when other therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective AND oral and nasal triptans are not appropriate.
- For the treatment of migraine<sup>1</sup> headache of severe<sup>2</sup> or ultra severe<sup>2</sup> intensity when oral and nasal triptans are not appropriate.

#### Clinical Notes:

1. <sup>1</sup>As diagnosed based on current Canadian guidelines.
2. <sup>2</sup>Definitions:
  - Moderate - pain is distracting causing need to slow down and limit activities;
  - Severe - pain affects ability to concentrate and very difficult to continue with daily activities;
  - Ultra severe - unable to speak or think clearly; not able to function; likely lying down or sleeping

#### Claim Notes:

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - patients with >3 migraines/month on average despite prophylactic therapy may be considered for up to a maximum of 12 doses / 30 days
- <sup>3</sup>Reimbursement will be available for a maximum quantity of triptan doses as outlined in criteria per 30 days regardless of the agent(s) used within the 30 day period.

### **SUNITINIB (SUTENT) 12.5mg, 25mg and 50mg capsules**

#### **1. Pancreatic Neuroendocrine Tumors (pNET)**

For the treatment of patients with progressive, unresectable, well or moderately differentiated, locally advanced or metastatic pancreatic neuroendocrine tumors (pNET) with an ECOG performance status of 0-2, until disease progression.

#### **2. Gastrointestinal Stromal Tumour (GIST)**

For the treatment of patients with c-KIT expressing (CD117+) unresectable or metastatic/recurrent gastrointestinal stromal tumour (GIST) who meet the criteria for imatinib and who have:

- Early progression (within 6 months) while on imatinib;
- Progression following treatment with optimum (escalated) doses of imatinib;
- Intolerance to imatinib

Clinical Notes:

- Response to sunitinib therapy should be assessed at least every six months and therapy should be discontinued when there is objective evidence of disease progression
- Sunitinib will not be reimbursed concomitantly with imatinib

Claim Note:

- The dose reimbursed will be 50mg per day (4 weeks on, 2 weeks off)

**3. Metastatic Renal Cell Carcinoma (MRCC)**

For patients with histologically confirmed metastatic renal cell carcinoma (MRCC), who require:

- First-line therapy for the treatment of MRCC, and the patient is either a favourable or intermediate risk according to the Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic score\*
- OR
- Second-line therapy for the treatment of MRCC, provided that disease progression has occurred after prior cytokine therapy (e.g. interferon; aldesleukin).

Renewal criteria:

- Written confirmation that the patient has benefited from therapy and is expected to continue to do so.

Clinical Note:

- The Memorial Sloan-Kettering Cancer Center (MSKCC) Prognostic Score categorizes patients into three risk groups according to the number of pre-treatment risk factors present: Favourable = none; Intermediate = one or two; Poor = three or more. Pre-treatment risk factors:
    - Low Karnofsky performance status (<80%)
    - Lactate Dehydrogenase level greater than 1.5 times the upper limit of normal
    - Hemoglobin level below the lower limit of normal
    - High corrected serum calcium level (>10 mg/dL or 2.5 mmol/L)
    - Interval of less than 1 year between diagnosis and treatment
- Reference: Motzer RJ, Bacik J, Murphy BA et al. Interferon-alfa as a comparative treatment for clinical trials of new therapies against advanced renal cell carcinoma. J Clin Oncol 2002;20;289-96.

Claim Notes:

- The prescribed dosage is 50mg daily for four weeks, followed by two weeks off. This dosage is repeated in six week cycles.
- Initial approval period: 1 year
- Renewal period: 1 year

**TACROLIMUS (PROTOPIC)  
0.03% ointment**

For children over 2 years of age with refractory atopic dermatitis.

Claim Note:

- Approvals will be given for up to twelve months at a time.

**TACROLIMUS (PROTOPIC)  
0.1% ointment**

For the treatment of adults with moderate to severe atopic dermatitis who have failed or are intolerant to a site appropriate strength of corticosteroid therapy (i.e. low potency for the face versus intermediate to high potency for the trunk and extremities).

**TEMOZOLOMIDE (TEMODAL and generic brands)  
5mg, 20mg, 100mg, 140mg and 250mg capsules**

For the treatment of newly diagnosed high grade glioma patients with a good performance status (Karnofsky performance status greater or equal to 60%) when used in combination with radiotherapy or as adjuvant therapy post-radiation up to a maximum of 6 cycles.

**TENOFOVIR (VIREAD)  
300mg tablet**

- For the treatment of adult patients who have experienced adverse events or virologic failure with nucleoside reverse transcriptase inhibitors.
- For the treatment of chronic hepatitis B infection in patients with cirrhosis documented on radiologic or histologic grounds and a HBV DNA concentration above 2000 IU/mL.

**TERBINAFINE HYDROCHLORIDE (LAMISIL and generic brands)  
250mg tablets**

- Treatment of onychomycosis
- Treatment of dermatophyte infection unresponsive to other treatments or unlikely to respond to other treatments due to the site or severity of the infection.

Claim Notes:

- approval limits payment for 6 weeks for the treatment of fingernail mycosis.
- approval limits payment for 12 weeks for the treatment of toenail mycosis.

**TERIFLUNOMIDE (AUBAGIO)  
14mg film-coated tablet**

For the treatment of relapsing-remitting multiple sclerosis (RRMS) in patients who meet the following criteria:

- Two disabling attacks of MS in the previous two years, and
- Ambulatory with or without aid (EDSS of less than or equal to 6.5)

Clinical Note:

- An attack is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 24 hours in the absence of fever, and preceded by stability for at least one month.

Claim Notes:

- Prescriptions written by New Brunswick neurologists do not require special authorization.

**TESTOSTERONE (ANDRODERM, ANDROGEL, TESTIM)  
12.2mg and 24.3mg patches, 2.5g and 5g packets, 1% gel  
TESTOSTERONE UNDECANOATE (ANDRIOL and generic brands)  
40 mg capsule**

For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of:

- Primary: cryptorchidism, Klinefelter's, orchiectomy, and other established causes
- Secondary: Pituitary-hypothalamic injury due to tumors, trauma, radiation

Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate free testosterone measurements before initiating any replacement therapy

Clinical Note:

- Older males with non-specific symptoms of fatigue, malaise, or depression who have low testosterone levels do not satisfy these criteria.

**THYROTROPIN ALPHA (THYROGEN)  
0.9mg/mL injection**

1. For on-going evaluation in patients who have documented evidence of thyroid cancer, have undergone appropriate surgical and/or medical management, and require monitoring for recurrence and metastatic disease. This includes:
  - The patient has failed to respond to, or relapsed during:
    - Primary use in patients with inability to raise an endogenous TSH level ( $\geq 25$  mu/L) with thyroid hormone withdrawal.
    - Primary use in patients with one of the following documented comorbidities in whom severe hypothyroidism could be life threatening:
      - unstable angina
      - recent myocardial infarction
      - class III-IV congestive heart failure
      - uncontrolled psychiatric illness
      - other medical condition in which the clinical course could lead to a potential life threatening situation
    - Secondary use in patients with previous thyroid hormone withdrawal resulting in a documented life threatening event.
2. As an adjunctive treatment as pre-therapeutic stimulation for radioiodine ablation of thyroid tissue remnants in patients maintained on thyroid hormone suppression therapy who have undergone near-total or total thyroidectomy for well-differentiated thyroid cancer without evidence of distant metastatic thyroid cancer.

**TICAGRELOR (BRILINTA)  
90mg tablet**

To be taken in combination with ASA 75mg -150mg daily<sup>a</sup> for patients with acute coronary syndrome (i.e. ST elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI), or unstable angina (UA), as follows:

**STEMI<sup>b,c</sup>**

- STEMI patients undergoing primary PCI

**NSTEMI or UA<sup>b,c</sup>**

- Presence of high risk features irrespective of intent to perform revascularization:
  - High GRACE risk score (>140)
  - High TIMI risk score (5-7)
  - Second ACS within 12 months
  - Complex or extensive coronary artery disease e.g. diffuse three vessel disease
  - Definite documented cerebrovascular or peripheral vascular disease
  - Previous CABG
- OR
- Undergoing PCI + high risk angiographic anatomy<sup>d</sup>

Clinical Notes:

1. <sup>a</sup> Co-administration of ticagrelor with high maintenance dose ASA (>150mg daily) is not recommended.
2. <sup>b</sup> In the PLATO study more patients on ticagrelor experienced non CABG related major bleeding than patients on clopidogrel, however, there was no difference between the rate of overall major bleeding, between patients treated with ticagrelor and those treated with clopidogrel. As with all other antiplatelet treatments the benefit/risk ratio of antithrombotic effect vs. bleeding complications should be evaluated.
3. <sup>c</sup> Ticagrelor is contraindicated in patients with active pathological bleeding, in those with a history of intracranial hemorrhage and moderate to severe hepatic impairment.
4. <sup>d</sup> High risk angiographic anatomy is defined as any of the following: left main stenting, high risk bifurcation stenting (i.e., two-stent techniques), long stents ≥ 38 mm or overlapping stents, small stents ≤ 2.5 mm in patients with diabetes.

Claim Notes:

- Approval will be for a maximum of 12 months.
- Prescriptions written by invasive (interventional) cardiologists do not require special authorization.

**TINZAPARIN SODIUM (INNOHEP)  
10,000IU/mL multidose vials and pre-filled syringes  
20,000IU/mL multidose vials and pre-filled syringes**

See criteria under [Low Molecular Weight Heparins](#)

**TIOTROPIUM (SPIRIVA)  
18mcg capsule for inhalation**

**Chronic Obstructive Pulmonary Disease**

- For the treatment of chronic obstructive pulmonary disease (COPD) if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).
- Coverage can be provided without a trial of short-acting agent if there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1 /FVC ratio < 0.7) and significant symptoms (i.e. Medical Research Council (MRC) Dyspnea Scale score of 3-5).
- Combination therapy with tiotropium AND a long-acting beta2-adrenergic agonist/inhaled corticosteroid (LABA/ICS) will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (i.e. MRC score of 3-5)
  - AND
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids.

Clinical Note:

- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale). Spirometry reports from any point in time will be accepted.



Medical Research Council (MRC) Dyspnea Scale

COPD Stage	Symptoms
MODERATE – MRC 3 to 4	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
SEVERE – MRC 5	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

**TIPRANAVIR (APTIVUS)  
250mg capsule**

For the treatment of adult patients with HIV-1 infection who are treatment experienced, have demonstrated failure to multiple protease inhibitors and in whom no other protease inhibitor is a treatment option.

**TIZANIDINE (ZANAFLEX and generic brands)  
4mg tablet**

For the treatment of spasticity caused by traumatic brain injury, multiple sclerosis (MS), spinal cord injury (SCI) or cerebral vascular accident (CVA) in patients in whom baclofen is contraindicated, ineffective or not tolerated.

**TOBRAMYCIN (TOBI)  
300mg/5mL solution for inhalation**

For the treatment of cystic fibrosis patients who do not tolerate injectable tobramycin when used for inhalation.

**TOCILIZUMAB (ACTEMRA)  
80mg, 200mg and 400mg single dose vials (20mg/mL)**

**Rheumatoid Arthritis**

For patients with moderate to severe active rheumatoid arthritis who:

- Have not responded to an adequate trial of combination therapy of at least two traditional DMARDs (disease-modifying antirheumatic drugs). Combination DMARD therapy must include methotrexate unless contraindicated or not tolerated,  
OR
- Are not candidates for combination DMARD therapy, must have had adequate trial of at least three traditional DMARDs in sequence, one of which must have been methotrexate unless contraindicated  
AND
- Have had an inadequate response to a tumour necrosis factor (TNF)-alpha antagonist.

Clinical Notes:

1. Requests for continuation of therapy must include information demonstrating clinical response.
2. No dose escalation permitted above 8 mg/kg every 4 weeks or a maximum dose of 800 mg per infusion for individuals whose body weight is more than 100 kg.
3. Will not be reimbursed in combination with other biologic agents.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Initial approval will be for 16 weeks at a dose of 4 mg/kg.

**Systemic Juvenile Idiopathic Arthritis (sJIA)**

For the treatment of active systemic juvenile idiopathic arthritis (sJIA), in patients 2 years of age or older, who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate) due to intolerance or lack of efficacy.

Clinical Notes:

1. Coverage will be approved for a dose of 12 mg/kg for patients weighing less than 30kg or 8 mg/kg for patients weighing greater than or equal to 30kg to a maximum of 800mg, administered every two weeks.
2. Continued coverage will be dependent on a positive patient response as determined by a pediatric rheumatologist.

Claim Notes:

- Must be prescribed by, or in consultation with, a pediatric rheumatologist.
- Initial approval period: 16 weeks
- Renewal period: 1 year

**TOLTERODINE (DETROL)  
1mg and 2mg tablets**

For the treatment of overactive bladder with symptoms of urgency, urgency incontinence, and urinary frequency, in patients who have not tolerated a reasonable trial of immediate release oxybutynin.

Clinical Note:

- Requests for the treatment of stress incontinence will not be considered.

Claim Note:

- If the patient has had a claim for oxybutynin in the previous 24 months, the adjudication system will recognize this information and the claim for tolterodine will be automatically reimbursed without the need for a written special authorization request.

**TOLTERODINE (DETROL LA and generic brand)  
2mg and 4mg capsules**

For the treatment of overactive bladder with symptoms of urgency, urgency incontinence, and urinary frequency, in patients who have not tolerated a reasonable trial of immediate release oxybutynin.

Clinical Note:

- Requests for the treatment of stress incontinence will not be considered.

**TOPIRAMATE (TOPAMAX)  
15mg and 25mg sprinkle capsules**

- For the treatment of refractory epilepsy not well controlled with conventional therapy.
- To reduce the frequency of migraine headaches in adult patients who have failed an adequate trial of, or have contraindications to, beta blockers AND tricyclics for prophylaxis.

**TREPROSTINIL (REMODULIN)  
1mg/mL, 2.5mg/mL, 5mg/mL and 10mg/mL solution**

For the treatment of patients with primary pulmonary hypertension or pulmonary hypertension secondary to collagen vascular disease, with New York Heart Association class III or IV disease who have both:

1. failed to respond to non-prostanoid therapies  
AND
2. who are not candidates for epoprostenol therapy because of:
  - prior recurrent complications with central line access (e.g. infection, thrombosis)  
OR:
  - inability to operate the complicated delivery system of epoprostenol  
OR:
  - they reside in an area without ready access to medical care, which could complicate problems associated with an abrupt interruption of epoprostenol.

**TRAMETINIB (MEKINIST)  
0.5mg and 2mg tablets**

- As monotherapy for the first line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma with ECOG performance status of 0 or 1. If brain metastases are present, patients should be stable.
- As monotherapy for the second line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma for patients who have progressed after receiving chemotherapy treatment in the first line setting with ECOG performance status of 0 or 1. If brain metastases are present, patients should be stable.

Clinical Notes:

- Recommended Dose: 2 mg once daily until disease progression or development of unacceptable toxicity requiring discontinuation of trametinib.
- Trametinib will not be reimbursed in patients who have progressed on a prior BRAF therapy.

Claim Notes:

- Initial approval duration: 6 months
- Renewal approval duration: 6 months

**TRETINOIN (VESANOID)**  
**10mg capsule**

For the induction of remission in acute promyelocytic leukemia (APL) in previously untreated patients as well as in those who have relapsed after, or were refractory to, standard chemotherapy.

**TROSPIUM (TROSEC)**  
**20mg tablet**

For the treatment of overactive bladder with symptoms of urgency, urgency incontinence, and urinary frequency, in patients who have not tolerated a reasonable trial of immediate release oxybutynin.

Clinical Note:

- Requests for the treatment of stress incontinence will not be considered.

Claim Note:

- If the patient has had a claim for oxybutynin in the previous 24 months, the adjudication system will recognize this information and the claim for trospium will be automatically reimbursed without the need for a written special authorization request.

**URSODIOL (URSO and generic brand)**  
**250mg tablet**  
**URSODIOL (URSO DS and generic brand)**  
**500mg tablet**

For the management of cholestatic liver diseases, such as primary biliary cirrhosis.

**USTEKINUMAB (STELARA)**  
**45 mg/0.5 mL and 90 mg/1 mL pre-filled syringes**

For patients with severe, debilitating chronic plaque psoriasis who meet all of the following criteria:

- Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genital region;
- Failure to respond to, contraindications to, or intolerant to methotrexate and cyclosporine;
- Failure to respond to, intolerant to, or unable to access phototherapy

Clinical Notes:

1. Continuation of therapy beyond 16 weeks will be based on response. Patients not responding adequately at these time points should have treatment discontinued with no further treatment with the same agent recommended
2. An adequate response is defined as either:
  - $\geq 75\%$  reduction in Psoriasis Area Severity Index (PASI) score from when treatment started, or
  - $\geq 50\%$  reduction in PASI with a  $\geq 5$  point improvement in the Dermatology Life Quality Index (DLQI), or
  - A quantitative reduction in BSA affected with qualitative consideration of specific regions such as the face, hands, feet or genital region.
3. Concurrent use of >1 biologic will not be approved
4. Approval limited to a dose of 90 mg administered initially at weeks 0, 4 and 16, then 90 mg every 12 weeks thereafter, up to a year (if response criteria met at 16 weeks).

Claim Notes:

- Initial approval limited to 16 weeks.
- Must be prescribed by a dermatologist

**VALGANCICLOVIR (VALCYTE and generic brand)**  
**450mg tablet**  
**50mg/mL oral suspension**

- For the treatment of cytomegalovirus (CMV) retinitis in HIV positive patients on the advice of an infectious disease specialist.
- For the prevention of cytomegalovirus (CMV) disease in solid organ transplant patients at high-risk (i.e. donor CMV seropositive / recipient seronegative.)
- For the treatment of cytomegalovirus (CMV) disease in solid organ transplant patients.

Claim Note:

- Coverage will be for a maximum of 100 days post transplant. Requests from specific transplant centres for longer durations will be considered based on their standard protocols.

**VARENICLINE (CHAMPIX)  
0.5 mg and 1 mg tablets**

For smoking cessation treatment in adults 18 years of age and older.

A maximum of 12 weeks of standard therapy will be reimbursed annually without special authorization for either nicotine replacement therapy (patches/gum) or a non-nicotine, prescription smoking cessation drug (Champix or Zyban).

Claim Notes:

- A maximum of 168 tablets will be reimbursed annually without special authorization.
- Individuals who have a high probability of quitting with prolonged therapy may be approved under special authorization for 56 additional tablets. A maximum of three additional requests will be permitted annually (maximum of 168 additional tablets).
- All special authorization requests for additional tablets will require confirmation the individual has agreed, or is already registered with, the Smokers Helpline (1-877-513-5333) or is participating in another form of smoking cessation counselling to be specified.
- Requests for special authorization should be submitted on the [Request for Additional Smoking Cessation Therapy Form](#).

**Important Links:**

- [Smokers Helpline Referral Form](#)
- [Smokers Helpline Online](#)
- [On the road to quitting](#)
- [Quit4life](#)

**VEMURAFENIB (ZELBORAF)  
240mg film-coated tablet**

- For the first line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma who have an ECOG status performance of 0 or 1.
- For the second line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma who have an ECOG performance status of 0 or 1 and did not receive vemurafenib as first line treatment.

Clinical Notes:

- Recommended Dose: 960mg twice daily until disease progression or development of unacceptable toxicity requiring discontinuation of vemurafenib.
- Vemurafenib will not be reimbursed in patients who have progressed on a prior BRAF therapy

Claim Notes:

- Initial approval duration: 6 months
- Renewal approval duration: 6 months

**VIGABATRIN (SABRIL)  
500mg tablet and 500mg sachet**

Requests will be considered for:

- the adjunctive management of epilepsy which is not satisfactorily controlled by conventional therapy.
- initial monotherapy for the management of infantile spasms.

Claim Note:

- The maximum approved dose will be 4g/day

**VILANTEROL TRIFENATATE / FLUTICASONE FUROATE (BREO ELLIPTA)  
25mcg / 100mcg powder for inhalation**

**Chronic Obstructive Pulmonary Disease:**

- For the treatment of chronic obstructive pulmonary disease (COPD) if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e. salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).
- Coverage can be provided without a trial of short-acting agent if there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1 /FVC ratio < 0.7) and significant symptoms (i.e. Medical Research Council (MRC) Dyspnea Scale score of 3-5).
- Combination therapy with a long-acting muscarinic antagonist (LAMA) AND a long-acting beta2-adrenergic agonist/inhaled corticosteroid (LABA/ICS) will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (i.e. MRC score of 3-5)

AND

- there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids.

**Clinical Note:**

- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (i.e. MRC scale). Spirometry reports from any point in time will be accepted.

Medical Research Council (MRC) Dyspnea Scale

COPD Stage	Symptoms
MODERATE – MRC 3 to 4	Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.
SEVERE – MRC 5	Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

**VILANTEROL / UMECLIDINUM BROMIDE (ANORO ELLIPTA)  
25mcg/62.5mcg powder for inhalation**

For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients with an inadequate response to a long-acting beta-2 agonist (LABA) or long-acting anticholinergic (LAAC).

**Clinical Notes:**

- Moderate to severe COPD is defined by spirometry (post-bronchodilator) FEV<sub>1</sub> < 60% predicted and FEV<sub>1</sub>/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted.

If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e. Medical Research Council (MRC) Dyspnea Scale score of at least Grade 3). MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath (SOB) from COPD or has to stop for breath when walking at own pace on the level.

- Inadequate response is defined as persistent symptoms after at least 2 months of long-acting beta-2 agonist (LABA) or long-acting anticholinergic therapy (LAAC).

**VISMODEGIB (ERIVEDGE)  
150mg capsule**

**Initial Requests:**

- For patients with metastatic basal cell carcinoma (BCC) or with locally advanced BCC (including patients with basal cell nevus syndrome, i.e. Gorlin syndrome) who have measurable metastatic disease or locally advanced disease, which is considered inoperable or inappropriate for surgery<sup>1</sup> AND inappropriate for radiotherapy<sup>2</sup>
- Patient 18 years or age or older;
- Patient has ECOG ≤ 2
- Patient preference for oral therapy will not be considered

**Information Required**

Physicians must provide rationale for why surgery<sup>1</sup> AND radiation<sup>2</sup> cannot be considered

- The request must include a surgical consultation report that provides a preoperative/surgical evaluation why surgery is not appropriate for the patient;
- A consultation report as to why radiation therapy is not appropriate for the patient
- Both of the above evaluations must come from a physician who is not the requesting physician
- Confirmation that the patient has been discussed at a multi-disciplinary cancer conference or equivalent (e.g. Regional Tumour Board).

**Renewal criteria:**

- The physician has confirmed that the patient has not experienced disease progression while on Erivedge therapy.

**Clinical Notes:**

- <sup>1</sup>Considered inoperable or inappropriate for surgery for one of the following reasons:
  - Technically not possible to perform surgery due to size/location/invasiveness of BCC (either lesion too large or can be several small lesions making surgery not feasible)
  - Recurrence of BCC after two or more surgical procedures and curative resection unlikely
  - Substantial deformity and/or morbidity anticipated from surgery

- <sup>2</sup>Considered inappropriate for radiation for one of the following reasons:
  - Contraindication to radiation (e.g. Gorlin syndrome)
  - Prior radiation to lesion
  - Suboptimal outcomes expected due to size/location/invasiveness of BCC
- Dose: 150mg orally once daily taken until disease progression or unacceptable toxicity.

Claim Notes:

- Initial approval duration: 1 year
- Renewal approval duration: 1 year

**VORICONAZOLE (VFEND and generic brands)  
50mg and 200mg tablets**

- For the treatment of invasive aspergillosis.
- For culture proven invasive candidiasis with documented resistance to fluconazole.

Claim Notes:

- Must be prescribed in consultation with a specialist in infectious diseases or medical microbiology.
- Initial requests will be approved for a maximum of 3 months.

**ZAFIRLUKAST (ACCOLATE)  
20mg tablet**

For the treatment of moderate to severe asthma in patients who:

- Are not adequately controlled with moderate to high dose inhaled corticosteroids despite compliance with treatment
- AND
- Require increasing amounts of short-acting beta2-adrenergic agonists.

**ZANAMIVIR (RELENZA)  
5mg powder for inhalation**

For beneficiaries residing in long-term care facilities meeting the same criteria as for oseltamivir and for whom there is suspected or confirmed oseltamivir resistance, or for whom oseltamivir is contraindicated.

**ZOLEDRONIC ACID (ACLASTA and generic brands)  
5mg/100mL solution for infusion**

**Osteoporosis**

For the treatment of osteoporosis in postmenopausal women who were previously approved or would otherwise be eligible for coverage of oral bisphosphonates and who:

- Have experienced further significant decline in bone mineral density (BMD) after 1 year of continuous oral bisphosphonate therapy.
- OR
- Have experienced serious intolerance to oral bisphosphonates.
- OR
- Have a contraindication to oral bisphosphonates.

Clinical Note:

- Serious intolerance is defined as esophageal ulceration, erosion or stricture, or lower gastrointestinal symptoms severe enough to cause discontinuation of oral bisphosphonates, or swallowing disorders that will increase the risk of esophageal ulceration from oral bisphosphonates.

**Paget's Disease**

For the treatment of Paget's disease of bone.

**ZOLMITRIPTAN (ZOMIG and generic brands)  
2.5mg tablet  
ZOLMITRIPTAN (ZOMIG RAPIMELT and generic brands)  
2.5mg oral disintegrating tablets**

For the treatment of migraine<sup>1</sup> headache when:

- Migraines are moderate<sup>2</sup> in severity and other therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective,
- OR
- Migraine attacks are severe<sup>2</sup> or ultra severe<sup>2</sup>

Clinical Notes:

1. <sup>1</sup>As diagnosed based on current Canadian guidelines.
2. <sup>2</sup> Definitions:

- Moderate - pain is distracting causing need to slow down and limit activities;
- Severe - pain affects ability to concentrate and very difficult to continue with daily activities;
- Ultra severe - unable to speak or think clearly; not able to function; likely lying down or sleeping

Claim Notes:

- A maximum of 72 tablets will be reimbursed annually without special authorization. If additional medication is required within the year, a request should be made through special authorization.
- Patients with >3 migraines/month on average despite prophylactic therapy may be considered for up to a maximum of 12 doses / 30 days.

**ZOLMITRIPTAN (ZOMIG NASAL SPRAY)  
2.5mg and 5mg nasal sprays**

- For the treatment of migraine<sup>1</sup> headache of moderate<sup>2</sup> intensity when other therapies (e.g. NSAIDs, acetaminophen, DHE spray) are not effective AND patients have not responded to oral sumatriptan, zolmitriptan, rizatriptan and naratriptan.
- For the treatment of migraine<sup>1</sup> headache of severe<sup>2</sup> or ultra severe<sup>2</sup> intensity when patients have not responded to oral sumatriptan, zolmitriptan, rizatriptan and/or naratriptan.

Clinical Notes:

1. <sup>1</sup>As diagnosed based on current Canadian guidelines.
2. <sup>2</sup> Definitions:

- Moderate - pain is distracting causing need to slow down and limit activities;
- Severe - pain affects ability to concentrate and very difficult to continue with daily activities;
- Ultra severe - unable to speak or think clearly; not able to function; likely lying down or sleeping

Claim Notes:

- Coverage limited to 6 doses / 30 days<sup>3</sup>
  - patients with >3 migraines/month on average despite prophylactic therapy may be considered for up to a maximum of 12 doses / 30 days
- <sup>3</sup> Reimbursement will be available for a maximum quantity of triptan doses as outlined in criteria per 30 days regardless of the agent(s) used within the 30 day period.
- Special authorization for the products almotriptan 6.25mg and 12.5mg tablets, naratriptan 1mg and 2.5mg tablets, rizatriptan 5mg and 10mg tablets and wafers, sumatriptan 5mg and 20mg nasal spray and zolmitriptan 2.5mg tablets and orally dispersible tablets, 2.5mg and 5mg nasal spray will be considered as a set. Approvals will include all products in this list, however reimbursement will be available for a maximum quantity of one agent per month.

**ZUCLOPENTHIXOL (CLOPIXOL)  
10mg and 25mg tablets**

For the treatment of schizophrenia in patients with a history of failure, intolerance, or contraindication to at least one antipsychotic agent.